

# MISSOURI BOARD OF PHARMACY



## STATUTES & RULES

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# **BOP STATUTES**

## **CHAPTER 338**



# CHAPTER 338

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**338.010. Practice of pharmacy defined--auxiliary personnel--written protocol required, when--nonprescription drugs--rulemaking authority--therapeutic plan requirements--veterinarian defined.**

1. The "practice of pharmacy" means the interpretation, implementation, and evaluation of medical prescription orders, including any legend drugs under 21 U.S.C. Section 353; receipt, transmission, or handling of such orders or facilitating the dispensing of such orders; the designing, initiating, implementing, and monitoring of a medication therapeutic plan as defined by the prescription order so long as the prescription order is specific to each patient for care by a pharmacist; the compounding, dispensing, labeling, and administration of drugs and devices pursuant to medical prescription orders and administration of viral influenza, pneumonia, shingles and meningitis vaccines by written protocol authorized by a physician for persons twelve years of age or older as authorized by rule or the administration of pneumonia, shingles, and meningitis vaccines by written protocol authorized by a physician for a specific patient as authorized by rule; the participation in drug selection according to state law and participation in drug utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper records thereof; consultation with patients and other health care practitioners, and veterinarians and their clients about legend drugs, about the safe and effective use of drugs and devices; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management and control of a pharmacy. No person shall engage in the practice of pharmacy unless he is licensed under the provisions of this chapter. This chapter shall not be construed to prohibit the use of auxiliary personnel under the direct supervision of a pharmacist from assisting the pharmacist in any of his or her duties. This assistance in no way is intended to relieve the pharmacist from his or her responsibilities for compliance with this chapter and he or she will be responsible for the actions of the auxiliary personnel acting in his or her assistance. This chapter shall also not be construed to prohibit or interfere with any legally registered practitioner of medicine, dentistry, or podiatry, or veterinary medicine only for use in animals, or the practice of optometry in accordance with and as provided in sections 195.070 and 336.220 in the compounding, administering, prescribing, or dispensing of his or her own prescriptions.

2. Any pharmacist who accepts a prescription order for a medication therapeutic plan shall have a written protocol from the physician who refers the patient for medication therapy services. The written protocol and the prescription order for a medication therapeutic plan shall come from the physician only, and shall not come from a nurse engaged in a collaborative practice arrangement under section 334.104, or from a physician assistant engaged in a supervision agreement under section 334.735.

3. Nothing in this section shall be construed as to prevent any person, firm or corporation from owning a pharmacy regulated by sections 338.210 to 338.315, provided that a licensed pharmacist is in charge of such pharmacy.

4. Nothing in this section shall be construed to apply to or interfere with the sale of nonprescription drugs and the ordinary household remedies and such drugs or medicines as are normally sold by those engaged in the sale of general merchandise.

5. No health carrier as defined in chapter 376 shall require any physician with which they contract to enter into a written protocol with a pharmacist for medication therapeutic services.

6. This section shall not be construed to allow a pharmacist to diagnose or independently prescribe pharmaceuticals.

7. The state board of registration for the healing arts, under section 334.125, and the state board of pharmacy, under section 338.140, shall jointly promulgate rules regulating the use of protocols for prescription orders for medication therapy services and administration of viral influenza vaccines. Such rules shall require protocols to include provisions allowing for timely communication between the pharmacist and the referring physician, and any other patient protection provisions deemed appropriate by both boards. In order to take effect, such rules shall be approved by a majority vote of a quorum of each board. Neither board shall separately promulgate rules regulating the use of protocols for prescription orders for medication therapy services and administration of viral influenza vaccines. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2007, shall be invalid and void.

8. The state board of pharmacy may grant a certificate of medication therapeutic plan authority to a licensed pharmacist who submits proof of successful completion of a board-approved course of academic clinical study beyond a bachelor of science in pharmacy, including but not limited to clinical assessment skills, from a nationally accredited college or university, or a certification of equivalence issued by a nationally recognized professional organization and approved by the board of pharmacy.

9. Any pharmacist who has received a certificate of medication therapeutic plan authority may engage in the designing, initiating, implementing, and monitoring of a medication therapeutic plan as defined by a prescription order from a physician that is specific to each patient for care by a pharmacist.

10. Nothing in this section shall be construed to allow a pharmacist to make a therapeutic substitution of a pharmaceutical prescribed by a physician unless authorized by the written protocol or the physician's prescription order.

11. "Veterinarian", "doctor of veterinary medicine", "practitioner of veterinary medicine", "DVM", "VMD", "BVSe", "BVMS", "BSe (Vet Science)", "VMB", "MRCVS", or an equivalent title means a person who has received a doctor's degree in veterinary medicine from an accredited school of veterinary medicine or holds an Educational Commission for Foreign Veterinary Graduates (EDFVG) certificate issued by the American Veterinary Medical Association (AVMA).

(RSMo 1939 § 10005, A.L. 1951 p. 737, A.L. 1989 S.B. 39, A.L. 1990 H.B. 1287, A.L. 2007 S.B. 195, A.L. 2009 S.B. 296, A.L. 2011 H.B. 412 merged with S.B. 325)

Prior revisions: 1929 § 13140; 1919 § 4712; 1909 § 5764

**338.013. Pharmacy technician to register with board of pharmacy, fees, application, renewal--refusal to issue, when--employee disqualification list maintained, use.**

1. Any person desiring to assist a pharmacist in the practice of pharmacy as defined in this chapter shall apply to the board of pharmacy for registration as a pharmacy technician. Such applicant shall be, at a minimum, legal working age and shall forward to the board the appropriate fee and written application on a form provided by the board. Such registration shall be the sole authorization permitted to allow persons to assist licensed pharmacists in the practice of pharmacy as defined in this chapter.

2. The board may refuse to issue a certificate of registration as a pharmacy technician to an applicant that has been adjudicated and found guilty, or has entered a plea of guilty or nolo contendere, of a violation of any state, territory or federal drug law, or to any felony or has violated any provision of subsection 2 of section 338.055. Alternately, the board may issue such person a registration, but may authorize the person to work as a pharmacy technician provided that person adheres to certain terms and conditions imposed by the board. The board shall place on the employment disqualification list the name of an applicant who the board has refused to issue a certificate of registration as a pharmacy technician, or the name of a person who the board has issued a certificate of registration as a pharmacy technician but has authorized to work under certain terms and conditions. The board shall notify the applicant of the applicant's right to file a complaint with the administrative hearing commission as provided by chapter 621, RSMo.

3. If an applicant has submitted the required fee and an application for registration to the board of pharmacy, the applicant for registration as a pharmacy technician may assist a licensed pharmacist in the practice of pharmacy as defined in this chapter. The applicant shall keep a copy of the submitted application on the premises where the applicant is employed. If the board refuses to issue a certificate of registration as a pharmacy technician to an applicant, the applicant shall immediately cease assisting a licensed pharmacist in the practice of pharmacy.

4. A certificate of registration issued by the board shall be conspicuously displayed in the pharmacy or place of business where the registrant is employed.

5. Every pharmacy technician who desires to continue to be registered as provided in this section shall, within thirty days before the registration expiration date, file an application for the renewal, accompanied by the fee prescribed by the board. The registration shall lapse and become null and void thirty days after the expiration date.

6. The board shall maintain an employment disqualification list. No person whose name appears on the employment disqualification list shall work as a pharmacy technician, except as otherwise authorized by the board. The board may authorize a person whose name appears on the employment disqualification list to work or continue to work as a pharmacy technician provided the person adheres to certain terms and conditions imposed by the board.

7. The board may place on the employment disqualification list the name of a pharmacy technician who has been adjudicated and found guilty, or has entered a plea of guilty or nolo contendere, of a violation of any state, territory or federal drug law, or to any felony or has violated any provision of subsection 2 of section 338.055.

8. After an investigation and a determination has been made to place a person's name on the employment disqualification list, the board shall notify such person in writing mailed to the person's last known address:

(1) That an allegation has been made against the person, the substance of the allegation and that an investigation has been conducted which tends to substantiate the allegation;

(2) That such person's name has been added in the employment disqualification list of the board;

(3) The consequences to the person of being listed and the length of time the person's name will be on the list; and

(4) The person's right to file a complaint with the administrative hearing commission as provided in chapter 621, RSMo.

9. The length of time a person's name shall remain on the disqualification list shall be determined by the board.

10. No hospital or licensed pharmacy shall knowingly employ any person whose name appears on the employee disqualification list, except that a hospital or licensed pharmacy may employ a person whose name appears on the employment disqualification list but the board has authorized to work under certain terms and conditions. Any hos-

pital or licensed pharmacy shall report to the board any final disciplinary action taken against a pharmacy technician or the voluntary resignation of a pharmacy technician against whom any complaints or reports have been made which might have led to final disciplinary action that can be a cause of action for discipline by the board as provided for in subsection 2 of section 338.055. Compliance with the foregoing sentence may be interposed as an affirmative defense by the employer. Any hospital or licensed pharmacy which reports to the board in good faith shall not be liable for civil damages.

(L. 1997 S.B. 141, A.L. 2004 S.B. 1122, A.L. 2009 S.B. 296)

**338.015. Patient's freedom of choice to obtain prescription services, waiver--consultation and advice.**

1. The provisions of sections 338.010 to 338.015 shall not be construed to inhibit the patient's freedom of choice to obtain prescription services from any licensed pharmacist. However, nothing in sections 338.010 to 338.315 abrogates the patient's ability to waive freedom of choice under any contract with regard to payment or coverage of prescription expense.

2. All pharmacists may provide pharmaceutical consultation and advice to persons concerning the safe and therapeutic use of their prescription drugs.

3. All patients shall have the right to receive a written prescription from their prescriber to take to the facility of their choice.

(L. 1990 H.B. 1287)

(1992) *The use of the word "may" in statute permits pharmacist to provide consultation and advice to customers but does not impose duty on pharmacists to monitor customer's use of prescription drugs. Kampe v. Howard Stark Professional Pharmacy Inc., 841 S.W.2d 223 (Mo.App.W.D.).*

**338.020. Application for license--requirements--examination--oath--penalty.**

Every person who shall hereafter desire to be licensed as a pharmacist shall file with the board of pharmacy an application setting forth his name and age, the place, or places, at which and the time spent in the study of the science and art of pharmacy, and the practical experience which the applicant has had under the direction of a legally licensed pharmacist, and shall appear at a time and place designated by the board of pharmacy and submit to an examination as to his qualifications for registration as a licensed pharmacist. Each application shall contain a statement that it is made under oath or affirmation and that its representations are true and correct to the best knowledge and belief of the person signing same, subject to the penalties of making a false affidavit or declaration.

(RSMo 1939 § 10006, A.L. 1947 V. I p. 277, A. 1949 H.B. 2075, A.L. 1981 S.B. 16, A.L. 1990 H.B. 1287)

Prior revisions: 1929 § 13141; 1919 § 4713; 1909 § 5765

**338.030. Applicant--requirements for qualification.**

An applicant for examination shall be twenty-one years of age and in addition shall furnish satisfactory evidence of his good moral character and have had one year practical experience under the supervision of a licensed pharmacist within a licensed pharmacy, or other location approved by the board, and shall be a graduate of a school or college of pharmacy whose requirements for graduation are satisfactory to and approved by the board of pharmacy. (RSMo 1939 § 10014, A. 1949 H.B. 2075, A.L. 1951 p. 737, A.L. 1981 S.B. 16, A.L. 1990 H.B. 1287, A.L. 2001 H.B. 567)

Prior revisions: 1929 § 13142; 1919 § 4714; 1909 § 5766

**338.035. Application, contents--intern pharmacist--board shall promulgate rules, procedure.**

1. Every person who desires to be licensed as an intern pharmacist shall file with the board of pharmacy an application, on a form to be provided by the board of pharmacy.

2. If an applicant for an intern pharmacist license has complied with the requirements of this section and with the rules and regulations of the board of pharmacy and is not denied a license on any of the grounds listed in section 338.055, the board of pharmacy may issue to him a license to practice as an intern pharmacist.

3. Any intern pharmacist who wishes to renew his license shall within thirty days before the license expiration date file an application for a renewal.

4. A licensed intern pharmacist may practice pharmacy only under the direct supervision of a pharmacist licensed by the board.

5. The board of pharmacy shall promulgate rules and regulations which shall further regulate the duties of intern pharmacists and shall set the amount of the fees which shall accompany the license and renewal applications for intern pharmacists.

6. No rule or portion of a rule promulgated under the authority of this chapter shall become effective unless it has been promulgated pursuant to the provisions of section 536.024, RSMo.

(L. 1990 H.B. 1287, A.L. 1993 S.B. 52, A.L. 1995 S.B. 3, A.L. 2007 S.B. 272)

**338.040. License issued without examination, when--reciprocity--equivalency examination--fees.**

1. The board of pharmacy shall issue licenses to practice pharmacy in the state without examination to persons who have been legally registered or licensed as pharmacists in other states. Any applicant for a license under this section shall present satisfactory evidence of qualifications equal to those required from licensees in this state, that he was registered or licensed by examination in another state, and that the standard of competence required in the other state is not lower than that required in this state; but no license shall be issued until the board is satisfied that the other state accords similar recognition to the licensees of this state. Applicants for license under this section shall, with their application, forward a fee for the license as is determined by the board of pharmacy.

2. The board may by rule and regulation require any applicant under subsection 1 of this section to successfully complete any equivalency examination, practical examination, or any examination on Missouri laws pursuant to any rule or regulation as promulgated by the board.

3. Any individual who is registered or licensed in a foreign country may be licensed under the provisions of sections 338.010 to 338.315 upon presentation of satisfactory evidence of qualifications equal to those required of licensees in this state.

4. The board may require any applicant under subsection 3 of this section to successfully complete any equivalency examination, practical examination or any examination on Missouri laws pursuant to any rule and regulation as promulgated by the board.

*(RSMo 1939 § 10008, A.L. 1961 p. 501, A.L. 1969 S.B. 390, A.L. 1981 S.B. 16, A.L. 1990 H.B. 1287)*

*Prior revisions: 1929 § 13144; 1919 § 4716; 1909 § 5768*

*(1974) Held that standards to be met by applicant for a reciprocal license are the standards that were in effect in this state at the time he was admitted in the state from which he is applying. Missouri State Board of Pharmacy v. Kennedy (A.), 511 S.W.2d 913.*

**338.043. Temporary license--eligibility--renewal.**

1. Notwithstanding any provision of law to the contrary, the board of pharmacy may grant a temporary license to an applicant who meets such requirements as the board may prescribe by rule and regulation.

2. The license shall be renewable at the discretion of and with the approval of the board of pharmacy. A temporary license fee shall accompany the original application for a temporary license and a similar amount shall be paid in the event the temporary license is renewed.

*(L. 1990 H.B. 1287, A.L. 1997 S.B. 141, A.L. 2001 H.B. 567)*

**338.050. Pharmacist license, issued when, period covered.**

If the applicant for license as a pharmacist has complied with all the requirements of sections 338.010 and 338.020, the board of pharmacy shall enroll his name upon the register of pharmacists and issue to him a license which shall entitle him to practice as a pharmacist for a period ending with the expiration date of the license.

*(RSMo 1939 § 10007, A. 1949 H.B. 2075, A.L. 1961 p. 501, A.L. 1971 S.B. 145, A.L. 1981 S.B. 16)*

*Prior revisions: 1929 § 13143; 1919 § 4715; 1909 § 5767*

**338.055. Denial, revocation or suspension of license, grounds for--expedited procedure--additional discipline authorized, when.**

1. The board may refuse to issue any certificate of registration or authority, permit or license required pursuant to this chapter for one or any combination of causes stated in subsection 2 of this section or if the designated pharmacist-in-charge, manager-in-charge, or any officer, owner, manager, or controlling shareholder of the applicant has committed any act or practice in subsection 2 of this section. The board shall notify the applicant in writing of the reasons for the refusal and shall advise the applicant of his or her right to file a complaint with the administrative hearing commission as provided by chapter 621.

2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621 against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:

(1) Use of any controlled substance, as defined in chapter 195, or alcoholic beverage to an extent that such use impairs a person's ability to perform the work of any profession licensed or regulated by this chapter;

(2) The person has been finally adjudicated and found guilty, or entered a plea of guilty or nolo contendere, in a criminal prosecution under the laws of any state or of the United States, for any offense reasonably related to the qualifications, functions or duties of any profession licensed or regulated under this chapter, for any offense an essential element of which is fraud, dishonesty or an act of violence, or for any offense involving moral turpitude, whether or not sentence is imposed;

(3) Use of fraud, deception, misrepresentation or bribery in securing any certificate of registration or authority, permit or license issued pursuant to this chapter or in obtaining permission to take any examination given or required pursuant to this chapter;

(4) Obtaining or attempting to obtain any fee, charge, tuition or other compensation by fraud, deception or misrepresentation;

(5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;

(6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

(7) Impersonation of any person holding a certificate of registration or authority, permit or license or allowing any person to use his or her certificate of registration or authority, permit, license, or diploma from any school;

(8) Denial of licensure to an applicant or disciplinary action against an applicant or the holder of a license or other right to practice any profession regulated by this chapter granted by another state, territory, federal agency, or country whether or not voluntarily agreed to by the licensee or applicant, including, but not limited to, surrender of the license upon grounds for which denial or discipline is authorized in this state;

(9) A person is finally adjudged incapacitated by a court of competent jurisdiction;

(10) Assisting or enabling any person to practice or offer to practice any profession licensed or regulated by this chapter who is not registered and currently eligible to practice under this chapter;

(11) Issuance of a certificate of registration or authority, permit or license based upon a material mistake of fact;

(12) Failure to display a valid certificate or license if so required by this chapter or any rule promulgated hereunder;

(13) Violation of any professional trust or confidence;

(14) Use of any advertisement or solicitation which is false, misleading or deceptive to the general public or persons to whom the advertisement or solicitation is primarily directed;

(15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government;

(16) The intentional act of substituting or otherwise changing the content, formula or brand of any drug prescribed by written or oral prescription without prior written or oral approval from the prescriber for the respective change in each prescription; provided, however, that nothing contained herein shall prohibit a pharmacist from substituting or changing the brand of any drug as provided under section 338.056, and any such substituting or changing of the brand of any drug as provided for in section 338.056 shall not be deemed unprofessional or dishonorable conduct unless a violation of section 338.056 occurs;

(17) Personal use or consumption of any controlled substance unless it is prescribed, dispensed, or administered by a health care provider who is authorized by law to do so.

3. After the filing of such complaint, the proceedings shall be conducted in accordance with the provisions of chapter 621. Upon a finding by the administrative hearing commission that the grounds, provided in subsection 2 of this section, for disciplinary action are met, the board may, singly or in combination, censure or place the person named in the complaint on probation on such terms and conditions as the board deems appropriate for a period not to exceed five years, or may suspend, for a period not to exceed three years, or revoke the license, certificate, or permit. The board may impose additional discipline on a licensee, registrant, or permittee found to have violated any disciplinary terms previously imposed under this section or by agreement. The additional discipline may include, singly or in combination, censure, placing the licensee, registrant, or permittee named in the complaint on additional probation on such terms and conditions as the board deems appropriate, which additional probation shall not exceed five years, or suspension for a period not to exceed three years, or revocation of the license, certificate, or permit.

4. If the board concludes that a licensee or registrant has committed an act or is engaging in a course of conduct which would be grounds for disciplinary action which constitutes a clear and present danger to the public health and safety, the board may file a complaint before the administrative hearing commission requesting an expedited hearing and specifying the activities which give rise to the danger and the nature of the proposed restriction or suspension of the licensee's or registrant's license. Within fifteen days after service of the complaint on the licensee or registrant, the administrative hearing commission shall conduct a preliminary hearing to determine whether the alleged activities of the licensee or registrant appear to constitute a clear and present danger to the public health and safety which justify that the licensee's or registrant's license or registration be immediately restricted or suspended. The burden of proving that the actions of a licensee or registrant constitute a clear and present danger to the public health and safety shall be upon the state board of pharmacy. The administrative hearing commission shall issue its decision immediately after the hearing and shall either grant to the board the authority to suspend or restrict the license or dismiss the action.

5. If the administrative hearing commission grants temporary authority to the board to restrict or suspend the licensee's or registrant's license, such temporary authority of the board shall become final authority if there is no

request by the licensee or registrant for a full hearing within thirty days of the preliminary hearing. The administrative hearing commission shall, if requested by the licensee or registrant named in the complaint, set a date to hold a full hearing under the provisions of chapter 621 regarding the activities alleged in the initial complaint filed by the board.

6. If the administrative hearing commission dismisses the action filed by the board pursuant to subsection 4 of this section, such dismissal shall not bar the board from initiating a subsequent action on the same grounds.

(L. 1971 S.B. 145, A.L. 1978 H.B. 933, A.L. 1981 S.B. 16, A.L. 1986 H.B. 999, A.L. 1998 H.B. 1601, et al., A.L. 2001 H.B. 567, A.L. 2004 S.B. 1122, A.L. 2011 H.B. 412 merged with S.B. 284)

**338.056. Generic substitutions may be made, when, form required for prescription blanks, exception--penalty.**

1. Except as provided in subsection 2 of this section\*, the pharmacist filling prescription orders for drug products prescribed by trade or brand name may select another drug product with the same active chemical ingredients of the same strength, quantity and dosage form, and of the same generic drug type, as determined by the United States Adopted Names and accepted by the Federal Food and Drug Administration. Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subsection 2 of this section\*. The pharmacist who selects the drug product to be dispensed pursuant to this section shall assume the same responsibility for selecting the dispensed drug product as would be incurred in filling a prescription for a drug product prescribed by generic name. The pharmacist shall not select a drug product pursuant to this section unless the product selected costs the patient less than the prescribed product.

2. A pharmacist who receives a prescription for a brand name drug may, unless requested otherwise by the purchaser, select a less expensive generically equivalent product under the following circumstances:

(1) If a written prescription is involved, the prescription form used shall have two signature lines at opposite ends at the bottom of the form. Under the line at the right side shall be clearly printed the words: "Dispense as Written". Under the line at the left side shall be clearly printed the words "Substitution Permitted". The prescriber shall communicate the instructions to the pharmacist by signing the appropriate line. No prescription shall be valid without the signature of the prescriber on one of these lines;

(2) If an oral prescription is involved, the practitioner or the practitioner's agent, communicating the instructions to the pharmacist, shall instruct the pharmacist as to whether or not a therapeutically equivalent generic drug may be substituted. The pharmacist shall note the instructions on the file copy of the prescription.

3. All prescriptions written in the state of Missouri by practitioners authorized to write prescriptions shall be on forms which comply with subsection 2 hereof.

4. Notwithstanding the provisions of subsection 2 of this section to the contrary, a pharmacist may fill a prescription for a brand name drug by substituting a generically equivalent drug when generic substitution is allowed in accordance with the laws of the state where the prescribing practitioner is located.

5. Violations of this section are infractions.

(L. 1978 H.B. 933, A.L. 1996 H.B. 1237)

*\*Words "of this section" do not appear in original rolls.*

**338.059. Prescriptions, how labeled.**

1. It shall be the duty of a licensed pharmacist or a physician to affix or have affixed by someone under the pharmacist's or physician's supervision a label to each and every container provided to a consumer in which is placed any prescription drug upon which is typed or written the following information:

- (1) The date the prescription is filled;
- (2) The sequential number;
- (3) The patient's name;
- (4) The prescriber's directions for usage;
- (5) The prescriber's name;
- (6) The name and address of the pharmacy;
- (7) The exact name and dosage of the drug dispensed;
- (8) There may be one line under the information provided in subdivisions (1) to (7) of this subsection stating "Refill" with a blank line or squares following or the words "No Refill";
- (9) When a generic substitution is dispensed, the name of the manufacturer or an abbreviation thereof shall appear on the label or in the pharmacist's records as required in section 338.100.

2. The label of any drug which is sold at wholesale in this state and which requires a prescription to be dispensed at retail shall contain the name of the manufacturer, expiration date, if applicable, batch or lot number and national drug code.

(L. 1971 S.B. 145, A.L. 1973 S.B. 42, A.L. 1978 H.B. 933, A.L. 1997 S.B. 141)

**338.060. Renewal of license or permit--late renewal or failure to renew, effect--continuing education requirements--inactive license issued when--changed to active, procedure.**

1. Every licensed pharmacist or permit holder who desires to continue in the practice of this profession shall, within thirty days before the license expiration date, file an application for the renewal, which application shall be accompanied by the fee prescribed in sections 338.010 to 338.198.

2. If any pharmacist fails, after the expiration of the pharmacist's license, to make application to the board for its renewal, the pharmacist's name shall be removed from the register of licensed pharmacists, and such person, in order to again become registered as a licensed pharmacist, shall be required to pay all delinquent fees. Any pharmacist who fails to renew the pharmacist's license within two years of its expiration and then desires to be preregistered shall be treated in the same manner as a person who has never been licensed. Any registered pharmacist whose certificate of registration has expired while the pharmacist has been engaged in active duty with the United States Army, United States Navy, United States Air Force, the Marine Corps, Coast Guard, or any other branch of the armed services or the state militia called into the service or training of the United States of America, or in training or education under the supervision of the United States preliminary to induction into the military services may have the pharmacist's certificate of registration renewed without paying any lapse, renewal or registration fee or without passing any examination, if within one year after the termination of such service, training or education, other than by dishonorable discharge, the pharmacist furnishes the board with an affidavit to the effect that the pharmacist has been so engaged and that the pharmacist's service, training or education has terminated.

3. Except as provided in subsection 5 of this section, when applying for a renewal of the license as required by the provisions of this section, each licensed pharmacist shall submit proof of the completion of at least fifteen hours of board-approved continuing education courses during each twelve-month period immediately preceding the date of the application for renewal of the license. The board shall prescribe the form to be completed. No license shall be renewed unless the holder thereof has complied with the provisions of this subsection.

4. The proof of completion of such continuing education shall be in such form as the board may require. The approved courses shall include those offered by correspondence, but the board shall approve all courses of instruction which may be used to satisfy the education requirements of subsection 3 of this section.

5. Each licensed pharmacist may, instead of submitting proof of the completion of the required continuing education courses, apply for an inactive license at the time the pharmacist makes application for the renewal of the pharmacist's license and pay the required renewal fee. An inactive license shall then be issued, and may be renewed biennially. While the inactive license is in effect the pharmacist shall not practice pharmacy. The inactive license may be changed to a regular license without other examination whenever the pharmacist submits proof of the completion of continuing education courses for the total amount of such courses not completed since the pharmacist was last licensed on an active basis.

*(RSMo 1939 § 10009, A.L. 1943 p. 521, A.L. 1947 V. I p. 277, A. 1949 H.B. 2075, A.L. 1951 p. 737, A.L. 1981 S.B. 16, A.L. 1984 S.B. 478, A.L. 1997 S.B. 141, A.L. 1999 H.B. 343)*

*Prior revisions: 1929 § 13145; 1919 § 4717; 1909 § 5769*

**338.065. Disciplinary hearings--grounds for discipline.**

1. At such time as the final trial proceedings are concluded whereby a licensee or registrant, or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit, or license, has been adjudicated and found guilty, or has entered a plea of guilty or nolo contendere, in a felony prosecution pursuant to the laws of the state of Missouri, the laws of any other state, territory, or the laws of the United States of America for any offense reasonably related to the qualifications, functions or duties of a licensee, permittee, or registrant pursuant to this chapter or any felony offense, an essential element of which is fraud, dishonesty or an act of violence, or for any felony offense involving moral turpitude, whether or not sentence is imposed, the board of pharmacy may hold a disciplinary hearing to singly or in combination censure or place the licensee, permittee, or registrant named in the complaint on probation on such terms and conditions as the board deems appropriate for a period not to exceed five years, or may suspend, for a period not to exceed three years, or revoke the license, certificate, registration or permit.

2. Anyone who has been revoked or denied a license, permit or certificate to practice in another state may automatically be denied a license or permit to practice in this state. However, the board of pharmacy may establish other qualifications by which a person may ultimately be qualified and licensed to practice in Missouri.

*(L. 1990 H.B. 1287, A.L. 1997 S.B. 141, A.L. 1999 H.B. 343, A.L. 2004 S.B. 1122)*

**338.067. Revocation and restoration of license--conditions.**

1. In any order of revocation, the board may provide that the person may not apply for reinstatement of his license for a period of time ranging from two to seven years following the date of the order of revocation. All stay orders

shall toll this time period.

2. Before restoring to good standing a license, certificate or permit issued under sections 338.010 to 338.315 which has been in a revoked, suspended or inactive state for any cause for more than two years, the board may require the applicant to attend such continuing pharmaceutical education courses and pass such examinations as the board may direct.

*(L. 1990 H.B. 1287)*

**338.070. Fees, amount, how set, collection, disposition--fund, created, use, funds transferred to general revenue, when.**

1. The board of pharmacy shall set the amount of the fees which this chapter authorizes and requires by rules and regulations promulgated pursuant to chapter 536, RSMo. The fees shall be set at a level to produce revenue which shall not substantially exceed the cost and expense of administering this chapter. All fees shall be paid before an applicant may be admitted to examination or his or her name placed upon the register of pharmacists, or before any license or permit, or any renewal thereof, is issued by the board.

2. All fees payable pursuant to the provisions of this chapter shall be collected by the division of professional registration and transmitted to the department of revenue for deposit in the state treasury to the credit of the fund to be known as the "Board of Pharmacy Fund".

3. The provisions of section 33.080, RSMo, to the contrary notwithstanding, money in this fund shall not be transferred and placed to the credit of general revenue until the amount in the fund at the end of the biennium exceeds two times the amount of the appropriation from the board's funds for the preceding fiscal year or, if the board requires by rule permit renewal less frequently than yearly, then three times the appropriation from the board's funds for the preceding fiscal year. The amount, if any, in the fund which shall lapse is that amount in the fund which exceeds the appropriate multiple of the appropriations from the board's funds for the preceding fiscal year.

*(RSMo 1939 § 10015, A.L. 1947 V. I p. 277, A.L. 1953 p. 613, A.L. 1961 p. 501, A.L. 1969 S.B. 390, A.L. 1981 S.B. 16, A.L. 1985 S.B. 99, A.L. 1997 S.B. 141)*

*Prior revisions: 1929 § 13151; 1919 § 4723; 1909 § 5775*

**338.080. Display of license or renewal required.**

Every license to practice as a pharmacist, and every permit issued to any person under the provisions of this chapter to establish a pharmacy, and every renewal of such license or permit, shall be conspicuously exposed in the pharmacy or place of business of which the pharmacist or other person to whom it is issued is the owner or manager or in which he is employed.

*(RSMo 1939 § 10009, A.L. 1943 p. 521, A.L. 1947 V. I p. 277, A. 1949 H.B. 2075, A.L. 1990 H.B. 1287)*

*Prior revisions: 1929 § 13145; 1919 § 4717; 1909 § 5769*

**338.090. Sale of poisons--regulations.**

1. It shall be unlawful for any person to retail any poisons enumerated in schedules "A" and "B", except as follows: Schedule "A"--arsenic and its preparations, biniodide of mercury, cyanide of potassium, hydrocyanic acid, strychnia, and all other poisonous vegetable alkaloids and their salts, and the essential oil of bitter almonds. Schedule "B"--opium and its preparations, except paregoric and other preparations of opium containing less than two grains to the ounce, aconite, bella donna, colchicum, conium, nux vomica, henbane, savin, ergot, cotton root, cantharides, creosote, veratrum, digitalis, and their pharmaceutical preparations, croton oil, chloroform, chloral hydrate, sulphate of zinc, corrosive sublimate, red precipitate, white precipitate, mineral acids, carbolic acid, oxalic acid, without labeling the box, vessel or paper in which the said poison is contained, and also the outside wrapper or cover with the name of the article, the word "poison" and the name and place of business of the seller.

2. Nor shall it be lawful for any person to sell or deliver any poisons enumerated in schedules "A" and "B" unless, upon due inquiry, it is found that the purchaser is aware of its poisonous character and represents that it is to be used for legitimate purposes. Nor shall it be lawful for any registered pharmacists to sell any poisons included in schedule "A" without, before delivering the same to the purchaser, causing an entry to be made in a book kept for that purpose, stating the date of sale, name and address of purchaser, the name of the poison sold, the purpose for which it was represented by the purchaser to be required and the name of the dispenser, such book to be always open for inspection by the proper authorities, and to be preserved for at least five years.

3. The provisions of this section shall not apply to the dispensing of poison in not unusual quantities or doses upon the prescription of practitioners of medicine.

*(RSMo 1939 § 10018, A. 1949 H.B. 2075)*

*Prior revisions: 1929 § 13152; 1919 § 4724; 1909 § 5776*

**CROSS REFERENCE:**

*Pesticides registration, RSMo 281.210 to 281.310*



**338.095. Prescription, drug order, defined--telephone prescription, defined--prescription and medical information may be provided, when.**

1. The terms "prescription" and "prescription drug order" are hereby defined as a lawful order for medications or devices issued and signed by an authorized prescriber within the scope of his professional practice which is to be dispensed or administered by a pharmacist or dispensed or administered pursuant to section 334.104, RSMo, to and for the ultimate user. The terms "prescription" and "drug order" do not include an order for medication requiring a prescription to be dispensed, which is provided for the immediate administration to the ultimate user or recipient.

2. The term "telephone prescription" is defined as an order for medications or devices transmitted to a pharmacist by telephone or similar electronic medium by an authorized prescriber or his authorized agent acting in the course of his professional practice which is to be dispensed or administered by a pharmacist or dispensed or administered pursuant to section 334.104, RSMo, to and for the ultimate user. A telephone prescription shall be promptly reduced to written or electronic medium by the pharmacist and shall comply with all laws governing prescriptions and record keeping.

3. A licensed pharmacist may lawfully provide prescription or medical information to a licensed health care provider or his agent who is legally qualified to administer medications and treatments and who is involved in the treatment of the patient. The information may be derived by direct contact with the prescriber or through a written protocol approved by the prescriber. Such information shall authorize the provider to administer appropriate medications and treatments.

4. Nothing in this section shall be construed to limit the authority of other licensed health care providers to prescribe, administer, or dispense medications and treatments within the scope of their professional practice.

5. It shall be an unauthorized practice of pharmacy and hence unlawful for any person other than the patient or the patient's authorized representative to accept a prescription presented to be dispensed unless that person is located on a premises licensed by the board as a pharmacy.

*(L. 1993 H.B. 564, A.L. 2007 S.B. 195)*

**338.100. Records required to be kept--requirements.**

1. Every permit holder of a licensed pharmacy shall cause to be kept in a uniform fashion consistent with this section a suitable book, file, or electronic recordkeeping system in which shall be preserved, for a period of not less than five years, the original or order of each drug which has been compounded or dispensed at such pharmacy, according to and in compliance with standards provided by the board, and shall produce the same in court or before any grand jury whenever lawfully required. A licensed pharmacy may maintain its prescription file on readable microfilm for records maintained over three years. After September, 1999, a licensed pharmacy may preserve prescription files on microfilm or by electronic media storage for records maintained over three years. The pharmacist in charge shall be responsible for complying with the permit holder's record-keeping system in compliance with this section. Records maintained by a pharmacy that contain medical or drug information on patients or their care shall be considered as confidential and shall only be released according to standards provided by the board. Upon request, the pharmacist in charge of such pharmacy shall furnish to the prescriber, and may furnish to the person for whom such prescription was compounded or dispensed, a true and correct copy of the original prescription. The file of original prescriptions kept in any format in compliance with this section, and other confidential records, as defined by law, shall at all times be open for inspection by board of pharmacy representatives. Records maintained in an electronic record-keeping system shall contain all information otherwise required in a manual record-keeping system. Electronic records shall be readily retrievable. Pharmacies may electronically maintain the original prescription or prescription order for each drug and may electronically annotate any change or alteration to a prescription record in the electronic record-keeping system as authorized by law; provided however, original written and faxed prescriptions shall be physically maintained on file at the pharmacy under state and federal controlled substance laws.

2. An institutional pharmacy located in a hospital shall be responsible for maintaining records of the transactions of the pharmacy as required by federal and state laws and as necessary to maintain adequate control and accountability of all drugs. This shall include a system of controls and records for the requisitioning and dispensing of pharmaceutical supplies where applicable to patients, nursing care units and to other departments or services of the institution. Inspection performed pursuant to this subsection shall be consistent with the provisions of section 197.100.

3. "Electronic record-keeping system", as used in this section, shall mean a system, including machines, methods of organization, and procedures, that provides input, storage, processing, communications, output, and control functions for digitized images of original prescriptions.

*(RSMo 1939 § 10019, A.L. 1971 S.B. 145, A.L. 1990 H.B. 1287, A.L. 1997 S.B. 141, A.L. 1999 H.B. 343, A.L. 2010 S.B. 754)*

*Prior revisions: 1929 § 13153; 1919 § 4725; 1909 § 5777*

**338.110. Board of pharmacy, members, qualifications, terms.**

1. The board of pharmacy shall consist of seven persons not connected with any school of pharmacy. Six members shall be licensed as pharmacists and actively engaged in the practice of pharmacy within this state, and at least one of these shall be a person who provides, on a full-time basis, pharmaceutical services to a hospital, skilled nursing facility or an intermediate care facility. The other member shall be a voting public member. All members shall be appointed by the governor, with the approval of the senate, and shall hold their office for five years from the date of their appointment and until their successors shall have been appointed and qualified.

2. Annually the Missouri Pharmaceutical Association may submit to the director of the division of professional registration the names of five persons licensed as pharmacists within this state, and from this number, or from others, the governor, with the approval of the senate, shall appoint one member to fill the vacancy annually occurring in the board of pharmacy, and vacancies occurring from any other cause shall be filled in like manner. This subsection shall not apply to public member vacancies.

3. The public member shall be at the time of his or her appointment a citizen of the United States; a resident of this state for a period of one year and a registered voter; a person who is not and never was a member of any profession licensed or regulated pursuant to this chapter or the spouse of such person; and a person who does not have and never has had a material, financial interest in either the providing of the professional services regulated by this chapter, or an activity or organization directly related to any profession licensed or regulated pursuant to this chapter. All members, including public members, shall be chosen from lists submitted by the director of the division of professional registration. The duties of the public member shall not include the determination of the technical requirements to be met for licensure or whether any person meets such technical requirements or of the technical competence or technical judgment of a licensee or a candidate for licensure.

*(RSMo 1939 § 10010, A. 1949 H.B. 2075, A.L. 1981 S.B. 16, A.L. 1999 H.B. 343)*

*Prior revisions: 1929 § 13146; 1919 § 4718; 1909 § 5770*

**CROSS REFERENCE:**

*Public member, additional duties, RSMo 620.132*

**338.120. Board of pharmacy--organization.**

Annually the board of pharmacy shall organize by the election of a president and vice president who shall hold their offices for one year and until their successors shall have been elected and qualified.

*(RSMo 1939 § 10011, A.L. 1981 S.B. 16, A.L. 1997 S.B. 141)*

*Prior revisions: 1929 § 13147; 1919 § 4719; 1909 § 5771*

**338.130. Compensation of board members, personnel.**

1. Each member of the board shall receive as compensation an amount set by the board not to exceed fifty dollars for each day devoted to the affairs of the board, and shall be entitled to reimbursement of the member's expenses necessarily incurred in the discharge of the member's official duties.

2. The board may employ such board personnel, as defined in subdivision (4) of subsection 10 of section 324.001, RSMo, as it deems necessary to carry out the provisions of this chapter. The compensation and expenses of such personnel and all expenses incurred by the board in carrying into execution the provisions of this chapter shall be paid out of the board of pharmacy fund upon a warrant on the state treasurer.

*(RSMo 1939 § 10017, A. 1949 H.B. 2075, A.L. 1961 p. 503, A.L. 1969 S.B. 390, A.L. 1981 S.B. 16, A.L. 1997 S.B. 141, A.L. 2008 S.B. 788)*

*Prior revisions: 1929 § 13149; 1919 § 4721; 1909 § 5773*

**338.132. Board of pharmacy, salary schedule for employees to be established.**

Any provision of the law to the contrary notwithstanding, the board of pharmacy shall prepare and maintain an equitable salary schedule for professional staff that are employees of the board. The positions and classification plan for personnel attributed to the inspection of licensed entities within this chapter shall allow for a comparison of such positions with similar positions in adjoining states. Board of pharmacy professional positions shall not be compensated at more than ninety percent parity for corresponding positions within adjoining states for pharmacists employed in those positions.

*(L. 2005 S.B. 177 § 1)*

**338.140. Board of pharmacy, powers, duties--advisory committee, appointment, duties--letters of reprimand, censure or warning.**

1. The board of pharmacy shall have a common seal, and shall have power to adopt such rules and bylaws not inconsistent with law as may be necessary for the regulation of its proceedings and for the discharge of the duties imposed pursuant to sections 338.010 to 338.198, and shall have power to employ an attorney to conduct prosecu-

tions or to assist in the conduct of prosecutions pursuant to sections 338.010 to 338.198.

2. The board shall keep a record of its proceedings.

3. The board of pharmacy shall make annually to the governor and, upon written request, to persons licensed pursuant to the provisions of this chapter a written report of its proceedings.

4. The board of pharmacy shall appoint an advisory committee composed of six members, one of whom shall be a representative of pharmacy but who shall not be a member of the pharmacy board, three of whom shall be representatives of wholesale drug distributors as defined in section 338.330, one of whom shall be a representative of drug manufacturers, and one of whom shall be a licensed veterinarian recommended to the board of pharmacy by the board of veterinary medicine. The committee shall review and make recommendations to the board on the merit of all rules and regulations dealing with pharmacy distributors, wholesale drug distributors, drug manufacturers, and veterinary legend drugs which are proposed by the board.

5. A majority of the board shall constitute a quorum for the transaction of business.

6. Notwithstanding any other provisions of law to the contrary, the board may issue letters of reprimand, censure or warning to any holder of a license or registration required pursuant to this chapter for any violations that could result in disciplinary action as defined in section 338.055.

*(RSMo 1939 § 10012, A.L. 1981 S.B. 16, A.L. 1989 S.B. 39, A.L. 1997 S.B. 141, A.L. 2011 H.B. 412 merged with S.B. 325)*

*Prior revisions: 1929 § 13148; 1919 § 4720; 1909 § 5772*

### **338.145. Board president may administer oaths and issue subpoenas--enforcement of subpoenas.**

1. The president of the board may, upon majority vote of the board, administer oaths, issue subpoenas duces tecum, and require production of documents and records from any person or entity not licensed by the board when such documents and records are not otherwise available to the board pursuant to the board's inspection authority granted in sections 338.100 and 338.150. Subpoenas duces tecum shall be served by a person authorized to serve subpoenas of courts of record. In lieu of requiring attendance of a person to produce original documents in response to a subpoena duces tecum, the board may require sworn copies of such documents to be filed with it or delivered to its designated representative.

2. The board may enforce its subpoenas duces tecum by applying to the circuit court of Cole County, the county of the investigation, hearing or proceeding, or any county where the records reside or may be found for an order upon any person who shall fail to obey a subpoena duces tecum to show cause why such subpoena duces tecum should not be enforced, which such order and a copy of the application therefor shall be served upon the person in the same manner as a summons in a civil action. If the circuit court shall, after a hearing, determine that the subpoena duces tecum should be sustained and enforced, such court shall proceed to enforce the subpoena duces tecum in the same manner as though the subpoena had been issued in a civil case in the circuit court.

*(L. 2004 S.B. 1122)*

### **338.150. Inspections by authorized representatives of board, where.**

Any person authorized by the board of pharmacy is hereby given the right of entry and inspection upon all open premises purporting or appearing to be drug or chemical stores, apothecary shops, pharmacies or places of business for exposing for sale, or the dispensing or selling of drugs, pharmaceuticals, medicines, chemicals or poisons or for the compounding of physicians' or veterinarians' prescriptions.

*(RSMo 1939 § 10016, A.L. 1951 p. 737, A.L. 1961 p. 503, A.L. 1980 H.B. 1266, A.L. 1981 S.B. 16, A.L. 2011 H.B. 412 merged with S.B. 325)*

### **338.155. Immunity from civil liability, when.**

1. Any person who in good faith and without malice reports, provides information, or cooperates in any manner with the board, or assists the board in any manner including, but not limited to, any applicant or licensee, whether or not the applicant or licensee is the subject of an investigation, record custodians, consultants, attorneys, board members, agents, employees, staff or expert witnesses, in the course of any investigation, hearing or other proceeding conducted by or before the board pursuant to the provisions of this chapter shall not be subject to an action for civil damages as a result of providing such information and cooperating with the board.

2. No physician or other authorized prescriber who, in good faith, cooperates with the board by writing a prescription or drug order at the request of the board pursuant to a routine inspection or a lawful investigation shall, by virtue of that cooperation, be in violation of this chapter or any drug laws of this state and shall be acting as an agent of the state and, as such, shall have sovereign immunity for those actions.

3. No licensee, registrant, permit holder, or other individual or entity subject to the board's jurisdiction who, in good faith, fills a prescription presented by the board as part of an inspection or investigation shall, by virtue of that act,

be in violation of this chapter or the drug laws of this state, provided the prescription is otherwise prepared and dispensed in a lawful manner.

(L. 2004 S.B. 1122)

**338.170. Title of pharmacist--used by whom.**

It shall be unlawful for any person not legally licensed as a pharmacist to take, use or exhibit the title of pharmacist, or licensed or registered pharmacist, or the title druggist or apothecary, or any other title or description of like import.

(RSMo 1939 § 10020, A.L. 1951 p. 737)

*Prior revisions: 1929 § 13154; 1919 § 4726; 1909 § 5778*

*(1968) Punitive damages were proper in case where it was alleged that defendant who was not registered pharmacist filled prescription without supervision of person who was registered pharmacist. Duensing v. Huscher (Mo.), 431 S.W.2d 169.*

**338.180. Prosecution of offenders.**

Upon receiving information that any provision of sections 338.010 to 338.190 has been or is being violated, the secretary of the board of pharmacy shall investigate the matter, and upon probable cause appearing, shall, under the direction of the board, file a complaint and prosecute the offender therefor. It shall be the duty of the prosecuting attorney, upon the request of the secretary, to take charge of and conduct such prosecutions.

(RSMo 1939 § 10013, A. 1949 H.B. 2075)

*Prior revisions: 1929 § 13150; 1919 § 4722; 1909 § 5774*

**338.185. Board has access to certain court records.**

After August 28, 1990, notwithstanding any other provisions of law, the board of pharmacy shall have access to records involving an applicant for a license or permit or renewal of a license or permit as provided within this chapter, where the applicant has been adjudicated and found guilty or entered a plea of guilty or nolo contendere in a prosecution under the laws of any state or of the United States for any offense reasonably related to the qualifications, functions, or duties of any profession licensed or regulated under this chapter, for any offense an essential element of which is fraud, dishonesty or an act of violence or for any offense involving moral turpitude, whether or not sentence is imposed.

(L. 1990 H.B. 1287)

**338.190. Violation of law by licensee--penalty.**

Any person who is licensed under this chapter who violates any provision of sections 338.010 to 338.190 shall, upon conviction, be adjudged guilty of a class A misdemeanor.

(RSMo 1939 § 10022, A.L. 1951 p. 737, A.L. 1981 S.B. 16, A.L. 1990 H.B. 1287)

*Prior revisions: 1929 § 13156; 1919 § 4728; 1909 § 5780*

**338.195. Violation of law by person not licensed--penalty.**

Any person, who is not licensed under this chapter, who violates any provision of sections 338.010 to 338.315 shall, upon conviction, be adjudged guilty of a class C felony.

(L. 1990 H.B. 1287)

**338.196. Prescription by practitioner licensed in another state, may be filled, requirement.**

Notwithstanding the provisions of section 338.056 to the contrary, a pharmacist may fill a prescription written by a practitioner licensed in a state other than Missouri according to the practitioner's direction as to generic substitution.

(L. 1991 H.B. 444 § 5)

**338.198. Pharmacist may fill prescription forwarded by authorized agent.**

Other provisions of law to the contrary notwithstanding, a pharmacist may fill a physician's prescription or the prescription of an advanced practice nurse working under a collaborative practice arrangement with a physician, when it is forwarded to the pharmacist by a registered professional nurse or registered physician's assistant or other authorized agent. The written collaborative practice arrangement shall specifically state that the registered professional nurse or registered physician assistant is permitted to authorize a pharmacist to fill a prescription on behalf of the physician.

(L. 1993 H.B. 564)

**338.210. Pharmacy defined--practice of pharmacy to be conducted at pharmacy location--rulemaking authority.**

1. Pharmacy refers to any location where the practice of pharmacy occurs or such activities are offered or provided by a pharmacist or another acting under the supervision and authority of a pharmacist, including every premises or

other place:

- (1) Where the practice of pharmacy is offered or conducted;
- (2) Where drugs, chemicals, medicines, any legend drugs under 21 U.S.C. Section 353, prescriptions, or poisons are compounded, prepared, dispensed or sold or offered for sale at retail;
- (3) Where the words "pharmacist", "apothecary", "drugstore", "drugs", and any other symbols, words or phrases of similar meaning or understanding are used in any form to advertise retail products or services;
- (4) Where patient records or other information is maintained for the purpose of engaging or offering to engage in the practice of pharmacy or to comply with any relevant laws regulating the acquisition, possession, handling, transfer, sale or destruction of drugs, chemicals, medicines, prescriptions or poisons.

2. All activity or conduct involving the practice of pharmacy as it relates to an identifiable prescription or drug order shall occur at the pharmacy location where such identifiable prescription or drug order is first presented by the patient or the patient's authorized agent for preparation or dispensing, unless otherwise expressly authorized by the board.

3. The requirements set forth in subsection 2 of this section shall not be construed to bar the complete transfer of an identifiable prescription or drug order pursuant to a verbal request by or the written consent of the patient or the patient's authorized agent.

4. The board is hereby authorized to enact rules waiving the requirements of subsection 2 of this section and establishing such terms and conditions as it deems necessary, whereby any activities related to the preparation, dispensing or recording of an identifiable prescription or drug order may be shared between separately licensed facilities.

5. If a violation of this chapter or other relevant law occurs in connection with or adjunct to the preparation or dispensing of a prescription or drug order, any permit holder or pharmacist-in-charge at any facility participating in the preparation, dispensing, or distribution of a prescription or drug order may be deemed liable for such violation.

6. Nothing in this section shall be construed to supersede the provisions of section 197.100.

*(L. 1951 p. 734 § 1(a), A.L. 2001 H.B. 567, A.L. 2011 H.B. 412 merged with S.B. 325)*

### **338.220. Operation of pharmacy without permit or license unlawful--application for permit, classifications, fee--duration of permit.**

1. It shall be unlawful for any person, copartnership, association, corporation or any other business entity to open, establish, operate, or maintain any pharmacy as defined by statute without first obtaining a permit or license to do so from the Missouri board of pharmacy. A permit shall not be required for an individual licensed pharmacist to perform nondispensing activities outside of a pharmacy, as provided by the rules of the board. A permit shall not be required for an individual licensed pharmacist to administer drugs, vaccines, and biologicals by protocol, as permitted by law, outside of a pharmacy. The following classes of pharmacy permits or licenses are hereby established:

- (1) Class A: Community/ambulatory;
- (2) Class B: Hospital outpatient pharmacy;
- (3) Class C: Long-term care;
- (4) Class D: Nonsterile compounding;
- (5) Class E: Radio pharmaceutical;
- (6) Class F: Renal dialysis;
- (7) Class G: Medical gas;
- (8) Class H: Sterile product compounding;
- (9) Class I: Consultant services;
- (10) Class J: Shared service;
- (11) Class K: Internet;
- (12) Class L: Veterinary.

2. Application for such permit or license shall be made upon a form furnished to the applicant; shall contain a statement that it is made under oath or affirmation and that its representations are true and correct to the best knowledge and belief of the person signing same, subject to the penalties of making a false affidavit or declaration; and shall be accompanied by a permit or license fee. The permit or license issued shall be renewable upon payment of a renewal fee. Separate applications shall be made and separate permits or licenses required for each pharmacy opened, established, operated, or maintained by the same owner.

3. All permits, licenses or renewal fees collected pursuant to the provisions of sections 338.210 to 338.370 shall be deposited in the state treasury to the credit of the Missouri board of pharmacy fund, to be used by the Missouri board of pharmacy in the enforcement of the provisions of sections 338.210 to 338.370, when appropriated for that purpose by the general assembly.

4. Class L: veterinary permit shall not be construed to prohibit or interfere with any legally registered practitioner of veterinary medicine in the compounding, administering, prescribing, or dispensing of their own prescriptions, or medicine, drug, or pharmaceutical product to be used for animals.

5. Except for any legend drugs under 21 U.S.C. Section 353, the provisions of this section shall not apply to the sale, dispensing, or filling of a pharmaceutical product or drug used for treating animals.

*(L. 1951 p. 734 § 1, A.L. 1969 S.B. 390, A.L. 1981 S.B. 16, A.L. 1989 S.B. 39, A.L. 1997 S.B. 141, A.L. 1999 H.B. 343, A.L. 2001 H.B. 567, A.L. 2004 S.B. 1122, A.L. 2007 H.B. 780 merged with S.B. 272, A.L. 2009 S.B. 296, A.L. 2011 H.B. 412 merged with S.B. 325)*

### **338.230. Disposition of fees.**

All fees collected under the provisions of sections 338.210 to 338.370 shall be deposited in the state treasury to the credit of the Missouri board of pharmacy fund, to be used by the Missouri board of pharmacy in the enforcement of the provisions of sections 338.210 to 338.370, when appropriated for that purpose by the general assembly.

*(L. 1951 p. 734 § 3, A.L. 1989 S.B. 39)*

### **338.240. Evidence required for issuance of permit.**

1. Upon evidence satisfactory to the said Missouri board of pharmacy:

(1) That the pharmacy for which a permit, or renewal thereof, is sought, will be conducted in full compliance with sections 338.210 to 338.300, with existing laws, and with the rules and regulations as established hereunder by said board;

(2) That the equipment and facilities of such pharmacy are such that it can be operated in a manner not to endanger the public health or safety;

(3) That such pharmacy is equipped with proper pharmaceutical and sanitary appliances and kept in a clean, sanitary and orderly manner;

(4) That the management of said pharmacy is under the supervision of either a registered pharmacist, or an owner or employee of the owner, who has at his or her place of business a registered pharmacist employed for the purpose of compounding physician's or veterinarian's prescriptions in the event any such prescriptions are compounded or sold;

(5) That said pharmacy is operated in compliance with the rules and regulations legally prescribed with respect thereto by the Missouri board of pharmacy, a permit or renewal thereof shall be issued to such persons as the said board of pharmacy shall deem qualified to conduct such pharmacy.

2. In lieu of a registered pharmacist as required by subdivision (4) of subsection 1 of this section, a pharmacy permit holder that only holds a class L veterinary permit and no other pharmacy permit may designate a supervising registered pharmacist who shall be responsible for reviewing the activities and records of the class L pharmacy permit holder as established by the board by rule. The supervising registered pharmacist shall not be required to be physically present on site during the business operations of a class L pharmacy permit holder identified in subdivision (5) of subsection 1 of this section when noncontrolled legend drugs under 21 U.S.C. Section 353 are being dispensed for use in animals, but shall be specifically present on site when any noncontrolled drugs for use in animals are being compounded.

*(L. 1951 p. 734 § 2, A.L. 2011 H.B. 412 merged with S.B. 325)*

### **338.250. Equipment required--manner of operation of pharmacy--compliance with state and federal laws required.**

No pharmacy shall be licensed under the provisions of this chapter unless it is equipped with proper pharmaceutical equipment and reference manuals, so that the practice of pharmacy may be accurately and properly performed. The board shall prescribe the minimum of technical equipment which the pharmacy shall at all times possess. Such requirements may vary, depending upon the population served, but shall be consistently and uniformly enforced. No permit shall be issued or renewed for the operation of a pharmacy unless the pharmacy shall be operated in a manner and according to the rules and regulations prescribed by law and by the Missouri board of pharmacy with respect to obtaining and maintaining such a permit. Any pharmacy that receives or possesses drugs or devices shall be held responsible for compliance with all laws within this chapter as well as state and federal drug laws on all drugs received or possessed, including but not limited to drugs and devices received or possessed pursuant to a consignment arrangement.

*(L. 1951 p. 734 § 6, A.L. 1990 H.B. 1287, A.L. 1998 S.B. 940)*

**338.260. Business name not to include certain words unless supervised by pharmacist--historical names permitted--board of pharmacy may enforce.**

1. No person shall carry on, conduct or transact a business under a name which contains as part of the name the words "pharmacist", "pharmacy", "apothecary", "apothecary shop", "chemist shop", "drug store", "druggist", "drugs", "consultant pharmacist", or any word of similar or like import, unless the place of business is supervised by a licensed pharmacist.

2. Nothing in this chapter shall be construed to prevent any person from using a historical name in reference to any building, structure, or business so long as the person is not engaged in the practice of pharmacy as defined in section 338.010.

3. Notwithstanding the provisions of subsection 2 of this section, the board of pharmacy shall retain authority to enforce the provisions of subsection 1 of this section against any person offering for sale any naturopathic or homeopathic service or any herbal, nutritional, vitamin, dietary, mineral, or other supplement intended for human application, absorption, or consumption.

(L. 1951 p. 737 § 338.170, A.L. 1990 H.B. 1287, A.L. 2009 S.B. 394)

**338.270. Renewal applications to be made, when.**

Application blanks for renewal permits shall be mailed to each permittee on or before the first day of the month in which the permit expires and, if application for renewal of permit is not made before the first day of the following month, the existing permit, or renewal thereof, shall lapse and become null and void upon the last day of that month.

(L. 1951 p. 734 § 3, A.L. 1981 S.B. 16)

**338.280. Board of pharmacy, rules and regulations.**

The Missouri board of pharmacy may make such rules and regulations, not inconsistent with law, as may be necessary to carry out the purposes and enforce the provisions of sections 338.210 to 338.300.

(L. 1951 p. 734 § 4, A.L. 1971 S.B. 145, A.L. 1981 S.B. 16)

*(1987) Board of Pharmacy has no jurisdiction to regulate pharmacies in hospitals. Missouri Hospital Association v. Department of Consumer Affairs, Regulation and Licensing. 731 S.W.2d 262 (Mo.App.).*

*(1987) This section does not give the Board of Pharmacy the authority or jurisdiction to promulgate rules and regulations regarding in-hospital dispensing of drugs. Missouri Hospital Association v. Missouri Department of Consumer Affairs, Regulation and Licensing. 731 S.W.2d 262 (Mo.App.).*

**338.285. Board may file complaint, when, where filed.**

The board is hereby authorized and empowered, when examination or inspection of a pharmacy shall disclose to the board that the pharmacy is not being operated or conducted according to such legal rules and regulations and the laws of Missouri with respect thereto, to cause a complaint to be filed before the administrative hearing commission pursuant to chapter 621, RSMo, charging the holder of a permit to operate a pharmacy with conduct constituting grounds for discipline in accordance with section 338.055.

(L. 1971 S.B. 145, A.L. 2001 H.B. 567)

**338.290. Appeals from decision of board, notice of right.**

Any person denied a permit to establish or operate a pharmacy, or renewal of such permit, may appeal the decision of the board of pharmacy in the manner provided by law, and shall be notified of this right at the time of denial.

(L. 1951 p. 734 § 5, A.L. 1981 S.B. 16)

**338.300. Permit to be posted--not transferable.**

The permit, or renewal thereof, issued under the provisions of sections 338.210 to 338.300, and under which a pharmacy is being operated, shall be posted and exposed in a conspicuous place in such pharmacy; such permit or renewal of permit shall not be transferable.

(L. 1951 p. 734 § 3, A.L. 1981 S.B. 16)

**338.310. Violation, a misdemeanor.**

Every person who violates any provision of sections 338.210 to 338.300 shall, upon conviction thereof, be adjudged guilty of a class C misdemeanor.

(L. 1951 p. 734 § 7, A.L. 1981 S.B. 16)

**338.314. Inspection of pharmacy within certain facilities authorized--applicability of law.**

Nothing in sections 338.010 to 338.315 shall authorize the board of pharmacy to conduct an inspection of a long-

term care facility licensed under the provisions of chapter 198, RSMo, by the Missouri division of aging or its successors, except that the board of pharmacy may inspect any licensed pharmacy located within a long-term care facility. However, the provisions of sections 338.010 to 338.315 shall apply to all individuals licensed as a pharmacist and practicing pharmacy as defined in section 338.010.

(L. 1990 H.B. 1287)

**338.315. Receipt of drugs from unlicensed distributor or pharmacy, unlawful--penalty--pharmacy-to-pharmacy transfers, limit--legend drugs, inventories and records--rulemaking authority.**

1. Except as otherwise provided by the board by rule, it shall be unlawful for any pharmacist, pharmacy owner or person employed by a pharmacy to knowingly purchase or receive any legend drugs under 21 U.S.C. Section 353 from other than a licensed or registered drug distributor or licensed pharmacy. Any person who violates the provisions of this section shall, upon conviction, be adjudged guilty of a class A misdemeanor. Any subsequent conviction shall constitute a class D felony.

2. Notwithstanding any other provision of law to the contrary, the sale, purchase, or trade of a prescription drug by a pharmacy to other pharmacies is permissible if the total dollar volume of such sales, purchases, or trades are in compliance with the rules of the board and do not exceed five percent of the pharmacy's total annual prescription drug sales.

3. Pharmacies shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of legend drugs. Such records shall be maintained for two years and be readily available upon request by the board or its representatives.

4. The board shall promulgate rules to implement the provisions of this section. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2012, shall be invalid and void.

(L. 1989 S.B. 39, A.L. 2011 S.B. 325, A.L. 2012 H.B. 1563)

**338.320. Committee established, purpose, members, duties--sunset provision.**

1. There is hereby established the "Missouri Electronic Prior Authorization Committee" in order to facilitate, monitor, and report to the general assembly on Missouri-based efforts to contribute to the establishment of national electronic prior authorization standards. Such efforts shall include the Missouri-based electronic prior authorization pilot program established under subsection 5 of this section and the study and dissemination of information by the committee of the efforts of the National Council on Prescription Drug Programs (NCPDP) to develop national electronic prior authorization standards. The committee shall advise the general assembly and the department of insurance, financial institutions and professional registration as to whether there is a need for administrative rules to be promulgated by the department of insurance, financial institutions and professional registration as soon as practically possible.

2. The Missouri electronic prior authorization committee shall consist of the following members:

- (1) Two members of the senate, appointed by the president pro tempore of the senate;
- (2) Two members of the house of representatives, appointed by the speaker of the house of representatives;
- (3) One member from an organization of licensed physicians in the state;
- (4) One member who is a physician licensed in Missouri pursuant to chapter 334;
- (5) One member who is a representative of a Missouri pharmacy benefit management company;
- (6) One member from an organization representing licensed pharmacists in the state;
- (7) One member from the business community representing businesses on health insurance issues;
- (8) One member from an organization representing the leading research-based pharmaceutical and biotechnology companies;
- (9) One member from an organization representing the largest generic pharmaceutical trade association;
- (10) One patient advocate;
- (11) One member from an electronic prescription network that facilitates the secure electronic exchange of clinical information between physicians, pharmacies, payers, and pharmacy benefit managers and other health care providers;
- (12) One member from a Missouri-based electronic health records company;
- (13) One member from an organization representing the largest number of hospitals in the state;



- (14) One member from a health carrier as such term is defined under section 376.1350;
- (15) One member from an organization representing the largest number of health carriers in the state, as such term is defined under section 376.1350;
- (16) The director of the department of social services, or the director's designee;
- (17) The director of the department of insurance, financial institutions and professional registration, who shall be chair of the committee.

3. All of the members, except for the members from the general assembly, shall be appointed by the governor no later than September 1, 2012, with the advice and consent of the senate. The staff of the department of insurance, financial institutions and professional registration shall provide assistance to the committee.

4. The duties of the committee shall be as follows:

(1) Before February 1, 2019, monitor and report to the general assembly on the Missouri-based electronic prior authorization pilot program created under subsection 5 of this section including a report of the outcomes and best practices developed as a result of the pilot program and how such information can be used to inform the national standard-setting process;

(2) Obtain specific updates from the NCPDP and other pharmacy benefit managers and vendors that are currently engaged in pilot programs working toward national electronic prior authorization standards;

(3) Correspond and collaborate with the NCPDP and other such pilots through the exchange of information and ideas;

(4) Assist, when asked by the pharmacy benefit manager, with the development of the pilot program created under subsection 5 of this section with an understanding of information on the success and failures of other pilot programs across the country;

(5) Prepare a report at the end of each calendar year to be distributed to the general assembly and governor with a summary of the committee's progress and plans for the next calendar year, including a report on Missouri-based efforts to contribute to the establishment of national electronic prior authorization standards. Such annual report shall continue until such time as the NCPDP has established national electronic prior authorization standards or this section has expired, whichever is sooner. The first report shall be completed before January 1, 2013;

(6) Upon the adoption of national electronic prior authorization standards by the NCPDP, prepare a final report to be distributed to the general assembly and governor that identifies the appropriate Missouri administrative regulations, if any, that will need to be promulgated by the department of insurance, financial institutions and professional registration, in order to make those standards effective as soon as practically possible, and advise the general assembly and governor if there are any legislative actions necessary to the furtherance of that end.

5. The department of insurance, financial institutions and professional registration and the Missouri electronic prior authorization committee shall recruit a Missouri-based pharmacy benefits manager doing business nationally to volunteer to conduct an electronic prior authorization pilot program in Missouri. The pharmacy benefits manager conducting the pilot program shall ensure that there are adequate Missouri licensed physicians and an electronic prior authorization vendor capable and willing to participate in a Missouri-based pilot program. Such pilot program established under this section shall be operational by January 1, 2014. The department and the committee may provide advice or assistance to the pharmacy benefit manager conducting the pilot program but shall not maintain control or lead with the direction of the pilot program.

6. Pursuant to section 23.253 of the Missouri sunset act:

(1) The provisions of the new program authorized under this section shall sunset automatically six years after August 28, 2012, unless reauthorized by an act of the general assembly; and

(2) If such program is reauthorized, the program authorized under this section shall sunset automatically twelve years after the effective date of the reauthorization of this section; and

(3) This section shall terminate on September first of the calendar year immediately following the calendar year in which the program authorized under this section is sunset.

*(L. 2012 H.B. 1563 merged with H.B. 1827)*

*Sunset date 8-28-18, unless reauthorized*

*Termination date 9-1-19, unless reauthorized*

### **338.330. Definitions.**

As used in sections 338.300 to 338.370, the following terms mean:

(1) "Legend drug":

(a) Any drug or biological product:

a. Subject to Section 503(b) of the Federal Food, Drug and Cosmetic Act, including finished dosage forms and active ingredients subject to such Section 503(b); or

b. Required under federal law to be labeled with one of the following statements prior to being dispensed or delivered:

- (i) "Caution: Federal law prohibits dispensing without prescription";
- (ii) "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian"; or
- (iii) "Rx Only"; or

c. Required by any\* applicable federal or state law or regulation to be dispensed by prescription only or that is restricted to use or dispensed by practitioners only; and

(b) The term "drug", "prescription drug", or "legend drug" shall not include:

a. An investigational new drug, as defined by 21 CFR 312.3(b), that is being utilized for the purposes of conducting a clinical trial or investigation of such\*\* drug or product that is governed by, and being conducted under and pursuant to, 21 CFR 312, et. seq.;

b. Any drug product being utilized for the purposes of conducting a clinical trial or investigation that is governed by, and being conducted under and pursuant to, 21 CFR 312, et. seq.; or

c. Any drug product being utilized for the purposes of conducting a clinical trial or investigation that is governed or approved by an institutional review board subject to 21 CFR Part 56 or 45 CFR Part 46;

(2) "Out-of-state wholesale drug distributor", a wholesale drug distributor with no physical facilities located in the state;

(3) "Pharmacy distributor", any licensed pharmacy, as defined in section 338.210, engaged in the delivery or distribution of legend drugs to any other licensed pharmacy where such delivery or distribution constitutes at least five percent of the total gross sales of such pharmacy;

(4) "Wholesale drug distributor", anyone engaged in the delivery or distribution of legend drugs from any location and who is involved in the actual, constructive or attempted transfer of a drug or drug-related device in this state, other than to the ultimate consumer. This shall include, but not be limited to, drug wholesalers, repackagers and manufacturers which are engaged in the delivery or distribution of drugs in this state, with facilities located in this state or in any other state or jurisdiction. A wholesale drug distributor shall not include any common carrier or individual hired solely to transport legend drugs. Any locations where drugs are delivered on a consignment basis, as defined by the board, shall be exempt from licensure as a drug distributor, and those standards of practice required of a drug distributor but shall be open for inspection by board of pharmacy representatives as provided for in section 338.360.

(L. 1989 S.B. 39, A.L. 1993 S.B. 27, A.L. 1998 S.B. 940, A.L. 2011 H.B. 412 merged with S.B. 284 merged with S.B. 325)

Effective 6-10-11(H.B. 412)

7-07-11 (S.B. 325)

7-11-11 (S.B. 284)

\*Word "an" appears in original rolls of H.B. 412, 2011.

\*\*Word "that" appears in original rolls of H.B. 412, 2011.

### **338.333. License required, temporary licenses may be granted--out-of-state distributors, reciprocity allowed, when.**

1. Except as otherwise provided by the board of pharmacy by rule in the event of an emergency or to alleviate a supply shortage, no person or distribution outlet shall act as a wholesale drug distributor or pharmacy distributor without first obtaining license to do so from the Missouri board of pharmacy and paying the required fee. The board may grant temporary licenses when the wholesale drug distributor or pharmacy distributor first applies for a license to operate within the state. Temporary licenses shall remain valid until such time as the board shall find that the applicant meets or fails to meet the requirements for regular licensure. No license shall be issued or renewed for a wholesale drug distributor or pharmacy distributor to operate unless the same shall be operated in a manner prescribed by law and according to the rules and regulations promulgated by the board of pharmacy with respect thereto. Separate licenses shall be required for each distribution site owned or operated by a wholesale drug distributor or pharmacy distributor, unless such drug distributor or pharmacy distributor meets the requirements of section 338.335.

2. An agent or employee of any licensed or registered wholesale drug distributor or pharmacy distributor need not seek licensure under this section and may lawfully possess pharmaceutical drugs, if he is acting in the usual course of his business or employment.

3. The board may permit out-of-state wholesale drug distributors or out-of-state pharmacy distributors to be licensed as required by sections 338.210 to 338.370 on the basis of reciprocity to the extent that an out-of-state wholesale drug distributor or out-of-state pharmacy distributor both:

(1) Possesses a valid license granted by another state pursuant to legal standards comparable to those which must be met by a wholesale drug distributor or pharmacy distributor of this state as prerequisites for obtaining a license under the laws of this state; and

(2) Distributes into Missouri from a state which would extend reciprocal treatment under its own laws to a wholesale drug distributor or pharmacy distributor of this state.

*(L. 1989 S.B. 39 § 338.340, A.L. 2010 H.B. 2226, et al., A.L. 2012 H.B. 1563)*

**338.335. Separate licenses required, when--exemptions.**

1. Separate licenses shall be required for each distribution site owned or operated by a wholesale drug distributor or pharmacy distributor unless drugs are delivered only on a consignment basis as defined by the board, or the entity meets the requirements of subsection 2 of this section.

2. A wholesale drug distributor distributing drug-related devices in Missouri is not required to obtain a license from the board for out-of-state distribution sites owned by the wholesale drug distributor if:

(1) The wholesale drug distributor has one or more distribution sites located in Missouri, and all such in-state distribution sites receiving shipments of drug-related devices are licensed by the board as a distributor;

(2) The wholesale drug distributor's out-of-state distribution sites shipping to the in-state distribution site are in compliance with their respective state's licensing laws;

(3) The wholesale drug distributor's out-of-state distribution sites that deliver drug-related devices regulated by the board into Missouri for patient use deliver such devices only to the licensed wholesale drug distributor's in-state distribution site.

3. A Missouri wholesale drug distributor receiving shipments of drug-related devices from an out-of-state facility that is not required to be licensed as a distributor pursuant to subsection 2 of this section shall be responsible for all shipments received.

*(L. 1998 S.B. 940, A.L. 2010 H.B. 2226, et al.)*

**338.337. Out-of-state distributors, licenses required, exception.**

It shall be unlawful for any out-of-state wholesale drug distributor or out-of-state pharmacy acting as a distributor to do business in this state without first obtaining a license to do so from the board of pharmacy and paying the required fee, except as otherwise provided by section 338.335 and this section. Application for an out-of-state wholesale drug distributor's license under this section shall be made on a form furnished by the board. The issuance of a license under sections 338.330 to 338.370 shall not change or affect tax liability imposed by the Missouri department of revenue on any out-of-state wholesale drug distributor or out-of-state pharmacy. Any out-of-state wholesale drug distributor that is a drug manufacturer and which produces and distributes from a facility which has been inspected and approved by the Food and Drug Administration, maintains current approval by the federal Food and Drug Administration, and has provided a copy of the most recent Food and Drug Administration Establishment Inspection Report to the board, and which is licensed by the state in which the distribution facility is located, or, if located within a foreign jurisdiction, is authorized and in good standing to operate as a drug manufacturer within such jurisdiction, need not be licensed as provided in this section but such out-of-state distributor shall register its business name and address with the board of pharmacy and pay a filing fee in an amount established by the board.

*(L. 1989 S.B. 39 § 338.350, A.L. 2009 H.B. 191 merged with S.B. 296, A.L. 2010 H.B. 2226, et al.)*

**338.340. Sale of drugs, out-of-state distributor, license required.**

No person acting as principal or agent for any out-of-state wholesale drug distributor or out-of-state pharmacy distributor shall sell or distribute drugs in this state unless the wholesale drug distributor or pharmacy distributor has obtained a license pursuant to the provisions of sections 338.330 to 338.370.

*(L. 1989 S.B. 39 § 338.360)*

**338.343. Records to be maintained and be available for board inspection.**

Any licensee licensed under the provisions of sections 338.330 to 338.340 must maintain required records to guarantee security, storage and accountability. These records shall be available for inspection by the board.

*(L. 1989 S.B. 39 § 338.370, A.L. 1993 S.B. 27)*

**338.347. Renewal of license, application.**

Application blanks for renewal of license shall be mailed to each licensee on or before the first day of the month in which the license expires and, if application for renewal of license with required fee is not made before the first day of the following month, the existing license, or renewal thereof, shall lapse and become null and void upon the last day of that month.

*(L. 1989 S.B. 39 § 338.380)*

**338.350. Board of pharmacy to promulgate rules and regulations--procedure.**

The Missouri board of pharmacy may make such rules and regulations, not inconsistent with law, as may be necessary to carry out the purposes and enforce the provisions of sections 338.330 to 338.370. Such rules and regulations shall not be contrary to or more restrictive than any laws or rules pertaining to practices which are regulated by the federal Food and Drug Administration or the federal Drug Enforcement Administration when the laws or rules specifically state what requirements must be met for compliance. As used in this section, rules of the federal government shall not include guidelines or policies that may be enacted by federal agencies. No rule or portion of a rule promulgated under the authority of this chapter shall become effective unless it has been promulgated pursuant to the provisions of section 536.024, RSMo.

*(L. 1989 S.B. 39 § 338.390, A.L. 1993 S.B. 27 merged with S.B. 52, A.L. 1995 S.B. 3)*

**338.353. Discipline of licensee, grounds--procedure--administrative hearing commission to conduct hearing.**

1. The board of pharmacy is hereby authorized and empowered, when complaints, examinations or inspection of a wholesale drug distributor or pharmacy distributor disclose to the board that a wholesale drug distributorship or pharmacy distributorship is not being operated or conducted according to such legal rules and regulations and the laws of Missouri or any other state or the federal government with respect thereto, to cause a complaint to be filed before the administrative hearing commission pursuant to chapter 621, RSMo, charging the holder of a license to operate a drug distributorship or pharmacy wholesale operation constituting grounds for discipline in accordance with section 338.055.

2. If the board concludes that a wholesale drug distributor or pharmacy distributor has committed an act or is engaging in a course of conduct which constitutes a clear and present danger to the public health and safety in Missouri, the board may file a complaint before the administrative hearing commission requesting an expedited hearing and specifying the activities which give rise to the danger and the nature of the proposed restriction or suspension of the wholesale drug distributor's or pharmacy distributor's license. Within fifteen days after service of the complaint on a wholesale drug distributor or pharmacy distributor, the administrative hearing commission shall conduct a preliminary hearing to determine whether the alleged activities of the wholesale drug distributor or pharmacy distributor appear to constitute a clear and present danger to the public health and safety which justify that the wholesale drug distributor's or pharmacy distributor's license be immediately restricted or suspended. The burden of proving that a wholesale drug distributor or pharmacy distributor is a clear and present danger to the public health and safety shall be upon the state board of pharmacy. The administrative hearing commission shall issue its decision immediately after the hearing and shall either grant to the board the authority to suspend or restrict the license or dismiss the action.

3. If the administrative hearing commission grants temporary authority to the board to restrict or suspend the wholesale drug distributor's or pharmacy distributor's license, such temporary authority of the board shall become final authority if there is no request by the wholesale drug distributor or pharmacy distributor for a full hearing within thirty days of the preliminary hearing. The administrative hearing commission shall, if requested by the wholesale drug distributor or pharmacy distributor named in the complaint, set a date to hold a full hearing under the provisions of chapter 621, RSMo, regarding the activities alleged in the initial complaint filed by the board.

4. If the administrative hearing commission dismisses the action filed by the board pursuant to subsection 2 of this section, such dismissal shall not bar the board from initiating a subsequent action on the same grounds.

*(L. 1989 S.B. 39 § 338.395, A.L. 2001 H.B. 567)*

**338.357. Sanction imposed by board, when.**

Any probation, restriction, suspension or revocation imposed on a licensee by the board of pharmacy for violations of this chapter shall be determined by the board upon a finding in favor of the board following the hearing held pursuant to section 338.353.

*(L. 1989 S.B. 39 § 338.400)*

**338.360. Inspection of premises allowed, when.**

Any person authorized by the board of pharmacy is hereby given the right of entry for inspection during normal business hours upon all open premises purporting or appearing to be used by a wholesale drug distributor or pharmacy distributor in Missouri. Any wholesale drug distributor who provides adequate documentation of the most recent inspection less than two years old by the Food and Drug Administration or other comparable state agency as determined by the board with a satisfactory rating shall be exempt from further inspection by the board of pharmacy. Such an exemption shall not bar the board of pharmacy from initiating an investigation pursuant to a public or governmental complaint received by the board of pharmacy regarding a wholesale drug distributor not licensed by the Food and Drug Administration.

*(L. 1989 S.B. 39 § 338.410, A.L. 1993 S.B. 27)*

**338.365. Injunction may be issued, when, procedure.**

1. Upon proper application by the board of pharmacy, a court of competent jurisdiction may grant an injunction, restraining order or other order as may be appropriate to enjoin a person from:

(1) Offering to engage or engaging in the performance of any acts or practices for which a certificate of registration or authority, permit or license is required by this chapter upon a showing that such acts or practices were performed or offered to be performed without a certificate of registration or authority, permit or license; or

(2) Engaging in any practice or business authorized by a certificate of registration or authority, permit or license issued pursuant to this chapter upon a showing that the holder presents a probability of serious danger to the health, safety or welfare of any resident of the state or client or patient.

2. Any such actions shall be commenced either in the county in which such conduct occurred or in the county in which defendant resides.

3. Any action brought pursuant to this section shall be in addition and not in lieu of any penalty provided by law and may be brought concurrently with other actions to enforce this chapter.

(L. 1989 S.B. 39 § 338.415, A.L. 1997 S.B. 141)

**338.370. Penalties.**

Every person who violates any provision of sections 338.333, 338.337, and 338.340 shall, upon conviction thereof, be adjudged guilty of a class C felony.

(L. 1989 S.B. 39 § 338.420)

**338.380. Refusal to issue a certificate, when--impaired license committee authorized, duties, procedures.**

1. As used in this section the term "committee" means the well-being committee established under subsection 3 of this section.

2. The board may refuse to issue any certificate of registration or authority, permit or license required under this chapter for one or any combination of causes stated in subsection 2 of section 338.055, or the board may, as a condition to issuing or renewing any such certificate of registration or authority, permit or license, require a person to submit himself or herself for identification, intervention, treatment, or rehabilitation by the well-being committee as provided in this section. The board shall notify the applicant in writing of the reasons for the refusal and shall advise the applicant of his or her right to file a complaint with the administrative hearing commission as provided by chapter 621, RSMo.

3. The board may establish an impaired licensee committee, to be designated as the "Well-being Committee", to promote the early identification, intervention, treatment, and rehabilitation of licensees identified within this chapter, who may be impaired by reasons of illness, substance abuse, or as a result of any physical or mental condition. The board may enter into a contractual agreement for the purpose of creating, supporting and maintaining such a committee. The board may promulgate rules subject to the provisions of this section to effectuate and implement any committee formed under this section. The board may expend appropriated funds necessary to provide for operational expenses of the committee formed under this section. Any member of the committee, as well as any administrator, staff member, consultant, agent or employee of the committee, acting within the scope of his or her duties and without actual malice and all other persons who furnish information to the committee in good faith and without actual malice, shall not be liable for any claim of damages as a result of any statement, decision, opinion, investigation or action taken by the committee or by any individual member of the committee.

4. All information, interviews, reports, statements, memoranda or other documents furnished to or produced by the committee, as well as communications to or from the committee, any findings, conclusions, interventions, treatment, rehabilitation, or other proceedings of the committee which in any way pertain to a licensee who may be, or who actually is, impaired shall be absolutely privileged and confidential.

5. All records and proceedings of the committee which pertain or refer to a licensee who may be, or who actually is, impaired shall be privileged and confidential and shall be used by the committee and its members only in the exercise of the proper function of the committee and shall not be considered public records under chapter 610, RSMo, and shall only be subject to discovery or introduction as evidence in any civil, criminal, or administrative proceedings except as provided in subsection 6 of this section.

6. The committee may disclose information relative to an impaired licensee only when:

(1) It is essential to disclose the information to further the intervention, treatment, or rehabilitation needs of the impaired licensee and only to those persons or organization with a need to know;

(2) Its release is authorized in writing by the impaired licensee;

(3) The committee is required to make a report to the board; or

(4) The information is subject to a court order.

7. In lieu of the pursuing discipline against a licensee for violating one or more causes stated in subsection 2 of sec-

tion 338.055, the board may enter into a diversion agreement with a licensee to refer the licensee to the committee under such terms and conditions as are agreed to by the board and licensee. The board shall enter into no more than two diversion agreements with any individual licensee. If the licensee violates a term or condition of a diversion agreement entered into under this section, the board may elect to pursue discipline against the licensee under chapter 621, RSMo, for the original conduct that resulted in the diversion agreement, or for any subsequent violation of subsection 2 of section 338.055. While the licensee participates in the committee, the time limitations of section 620.154, RSMo, shall toll under subsection 7 of section 620.154, RSMo. All records pertaining to diversion agreements are confidential and may only be released under subdivision (7) of subsection 14 of section 620.010, RSMo.

8. The committee shall report to the board the name of any licensee who fails to enter treatment within forty-eight hours following the provider's determination that the pharmacist needs treatment or any failure by a licensee to comply with the terms of a diversion agreement during inpatient or outpatient treatment or aftercare or report a licensee who resumes the practice of pharmacy before the treatment provider has made a clear determination that the pharmacist is capable of practicing according to acceptable and prevailing standards.

9. The board may disclose information and records to the committee to assist the committee in the identification, intervention, treatment, and rehabilitation of any licensee who may be impaired by reason of illness, substance abuse, or as the result of any physical or mental condition. The committee shall keep all information and records provided by the board confidential to the extent the board is required to treat the information and records as closed to the public under chapter 620, RSMo.

10. Any rule or portion of a rule, as that term is defined in section 536.010, RSMo, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536, RSMo, and, if applicable, section 536.028, RSMo. This section and chapter 536, RSMo, are non-severable and if any of the powers vested with the general assembly pursuant to chapter 536, RSMo, to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2007, shall be invalid and void.

(L. 2007 S.B. 195)

### **338.400. Standard of care, definitions, rules.**

1. As used in this section, the following terms shall mean:

(1) "Ancillary infusion equipment and supplies", the equipment and supplies required to infuse a blood clotting therapy product into a human vein, including syringes, needles, sterile gauze, field pads, gloves, alcohol swabs, numbing creams, tourniquets, medical tape, sharps or equivalent biohazard waste containers, and cold compression packs;

(2) "Assay", the amount of a particular constituent of a mixture or of the biological or pharmacological potency of a drug;

(3) "Bleeding disorder", a medical condition characterized by a deficiency or absence of one or more essential blood-clotting components in the human blood, including all forms of hemophilia, von Willebrand's disease, and other bleeding disorders that result in uncontrollable bleeding or abnormal blood clotting;

(4) "Blood clotting product", a medicine approved for distribution by the federal Food and Drug Administration that is used for the treatment and prevention of symptoms associated with bleeding disorders, including but not limited to recombinant Factor VII, recombinant-activated Factor VIIa, recombinant Factor VIII, plasma-derived Factor VIII, recombinant Factor IX, plasma-derived Factor IX, von Willebrand factor products, bypass products for patients with inhibitors, prothrombin complex concentrates; and activated prothrombin complex concentrates;

(5) "Home nursing services", specialized nursing care provided in the home setting to assist a patient in the reconstitution and administration of blood clotting products;

(6) "Home use", infusion or other use of a blood clotting product in a place other than a hemophilia treatment center, hospital, emergency room, physician's office, outpatient facility, or clinic;

(7) "Pharmacy", an entity engaged in practice of pharmacy as defined in section 338.010 that provides patients with blood clotting products and ancillary infusion equipment and supplies.

2. The Missouri state board of pharmacy shall promulgate rules governing the standard of care for pharmacies dispensing blood clotting therapies. Such rules shall include, when feasible, the standards established by the medical advisory committees of the patient groups representing the hemophilia and von Willebrand diseases, including but not limited to Recommendation 188 of the National Hemophilia Foundation's Medical and Scientific Advisory Council. Such rules shall include safeguards to ensure the pharmacy:

(1) Has the ability to obtain and fill a physician prescription as written of all brands of blood clotting products approved by the federal Food and Drug Administration in multiple assay ranges of low, medium, and high, as applicable, and vial sizes, including products manufactured from human plasma and those manufactured from recombinant technology techniques, provided manufacturer supply exists and payer authorization is obtained;

- (2) Provides for the shipment of prescribed blood clotting products to the patient within two business days or less for established patients and three business days or less for new patients in nonemergency situations;
- (3) Provides established patients with access to blood clotting products within twelve hours of notification by the physician of the patient's emergent need for blood clotting products;
- (4) Provides all ancillary infusion equipment and supplies necessary for established patients for administration of blood clotting products;
- (5) Has a pharmacist available twenty-four hours a day, seven days a week, every day of the year, either onsite or on call, to fill prescriptions for blood clotting products;
- (6) Provides patients who have received blood clotting products with a designated contact telephone number for reporting problems with a delivery or product;
- (7) Provides patients with notification of recalls and withdrawals of blood clotting products and ancillary infusion equipment within twenty-four hours of receipt of the notification; and
- (8) Provides containers for the disposal of hazardous waste, and provides\* patients with instructions on the proper collection, removal, and disposal of hazardous waste under state and federal law.

3. Notwithstanding the provisions of subsection 2 of this section, pharmacies and pharmacists shall exercise that degree of skill and learning ordinarily exercised by members of their profession in the dispensing and distributing of blood clotting products.

(L. 2011 H.B. 552)

*\*Word "provide" appears in original rolls.*

### **338.500. Gross retail prescriptions, tax imposed, definitions.**

1. In addition to all other fees and taxes required or paid, a tax is hereby imposed upon licensed retail pharmacies for the privilege of providing outpatient prescription drugs in this state. The tax is imposed upon the Missouri gross retail prescription receipts earned from filling outpatient retail prescriptions.

2. For purposes of sections 338.500 to 338.550:

(1) "Gross retail prescription receipts" shall mean all amounts received by a licensed pharmacy for its own account from the sale of outpatient prescription drugs in the state of Missouri but shall not include those sales shipped out of the state of Missouri and shall include the receipts from cost sharing, dispensing fees, and retail prescription drug sales;

(2) "Licensed pharmacy" shall have the same meaning as such term is defined in section 338.210;

(3) "Retail" means a sale for use or consumption and not for resale.

(L. 2002 S.B. 1248)

*Effective 6-19-02*

*Expires 9-30-11*

### **338.505. Formula for tax liability, rulemaking authority, appeals procedure.**

1. Each licensed retail pharmacy's tax shall be based on a formula set forth in rules promulgated by the department of social services. Any rule or portion of a rule, as that term is defined in section 536.010, RSMo, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536, RSMo, and, if applicable, section 536.028, RSMo. This section and chapter 536, RSMo, are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536, RSMo, to review, to delay the effective date or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2002, shall be invalid and void.

2. The director of the department of social services or the director's designee may prescribe the form and contents of any forms or other documents required by sections 338.500 to 338.550.

3. Notwithstanding any other provision of law to the contrary, appeals regarding the promulgation of rules pursuant to this section shall be made to the circuit court of Cole County. The circuit court of Cole County shall hear the matter as the court of original jurisdiction.

(L. 2002 S.B. 1248)

*Effective 6-19-02*

*Expires 9-30-11*

### **338.510. Records to be maintained, form--report of gross receipts, information--confidentiality of information.**

1. Each licensed retail pharmacy shall keep such records as may be necessary to determine gross retail prescription receipts.

2. The director of revenue may prescribe the form and contents of any forms or other documents required by this section.

3. Each licensed retail pharmacy shall report the gross retail prescription receipts to the department of revenue.

4. The department of revenue shall provide the department of social services with the information that is necessary to implement the provisions of sections 338.500 to 338.550.

5. The information obtained by the department of social services from the department of revenue shall be confidential and any employee of the department of social services who unlawfully discloses any such information for any other purpose, except as authorized by law, shall be subject to the penalties specified in section 32.057, RSMo. (L. 2002 S.B. 1248)

*Effective 6-19-02*

*Expires 9-30-11*

**338.515. Effective date of tax.**

The tax imposed by sections 338.500 to 338.550 shall become effective July 1, 2003, or the effective date of sections 338.500 to 338.550, whichever is later.

(L. 2002 S.B. 1248, A.L. 2003 H.B. 286)

*Effective 6-26-03*

*Expires 9-30-11*

**338.520. Calculation of tax liability--notification to pharmacies--quarterly adjustment authorized.**

1. The determination of the amount of tax due shall be the monthly gross retail prescription receipts reported to the department of revenue multiplied by the tax rate established by rule by the department of social services. Such tax rate may be a graduated rate based on gross retail prescription receipts and shall not exceed a rate of six percent per annum of gross retail prescription receipts; provided, that such rate shall not exceed one-tenth of one percent per annum in the case of licensed pharmacies of which eighty percent or more of such gross receipts are attributable to prescription drugs that are delivered directly to the patient via common carrier, by mail, or a courier service.

2. The department of social services shall notify each licensed retail pharmacy of the amount of tax due. Such amount may be paid in increments over the balance of the assessment period.

3. The department of social services may adjust the tax rate quarterly on a prospective basis. The department of social services may adjust more frequently for individual providers if there is a substantial and statistically significant change in their pharmacy sales characteristics. The department of social services may define such adjustment criteria by rule.

(L. 2002 S.B. 1248, A.L. 2003 H.B. 286 merged with H.B. 600)

*Effective 6-26-03 (H.B. 286)*

*7-01-03 (H.B. 600)*

*Expires 9-30-11*

**338.530. Offset against Medicaid payments due by pharmacy permitted, when.**

The director of the department of social services may offset the tax owed by a pharmacy against any Missouri Medicaid payment due such pharmacy, if the pharmacy requests such an offset. The amounts to be offset shall result, so far as practicable, in withholding from the pharmacy an amount substantially equal to the assessment due from the pharmacy. The office of administration and the state treasurer may make any fund transfers necessary to execute the offset.

(L. 2002 S.B. 1248)

*Effective 6-19-02*

*Expires 9-30-11*

**338.535. Remittance to department--pharmacy reimbursement allowance fund created.**

1. The pharmacy tax owed or, if an offset has been made, the balance after such offset, if any, shall be remitted by the pharmacy or the pharmacy's designee to the department of social services. The remittance shall be made payable to the director of the department of revenue and shall be deposited in the state treasury to the credit of the "Pharmacy Reimbursement Allowance Fund" which is hereby created to provide payments for services related to the Medicaid pharmacy program. All investment earnings of the fund shall be credited to the fund.

2. An offset authorized by section 338.530 or a payment to the pharmacy reimbursement allowance fund shall be accepted as payment of the obligation set forth in section 338.500.

3. The state treasurer shall maintain records showing the amount of money in the pharmacy reimbursement allowance fund at any time and the amount of investment earnings on such amount.

4. Notwithstanding the provisions of section 33.080, RSMo, to the contrary, any unexpended balance in the pharmacy reimbursement allowance fund at the end of the biennium shall not revert to the credit of the general revenue fund.

(L. 2002 S.B. 1248, A.L. 2009 H.B. 395 merged with H.B. 740)

*Effective 6-26-09 (H.B. 740)*



**338.540. Notice requirements--unpaid or delinquent taxes, procedure for collection--failure to pay taxes, effect of.**

1. The department of social services shall notify each pharmacy with a tax due of more than ninety days of the amount of such balance. If any pharmacy fails to pay its pharmacy tax within thirty days of such notice, the pharmacy tax shall be delinquent.

2. If any tax imposed pursuant to sections 338.500 to 338.550 is unpaid and delinquent, the department of social services may proceed to enforce the state's lien against the property of the pharmacy and compel the payment of such assessment in the circuit court having jurisdiction in the county where the pharmacy is located. In addition, the department of social services may cancel or refuse to issue, extend, or reinstate a Medicaid provider agreement to any pharmacy that fails to pay the tax imposed by section 338.500.

3. Failure to pay the tax imposed by section 338.500 shall be grounds for denial, suspension, or revocation of a license granted pursuant to this chapter. The department of social services may request the board of pharmacy to deny, suspend, or revoke the license of any pharmacy that fails to pay such tax.

(L. 2002 S.B. 1248)

Effective 6-19-02

Expires 9-30-11

**338.550. Expiration date of tax, when.**

1. The pharmacy tax required by sections 338.500 to 338.550 shall expire ninety days after any one or more of the following conditions are met:

(1) The aggregate dispensing fee as appropriated by the general assembly paid to pharmacists per prescription is less than the fiscal year 2003 dispensing fees reimbursement amount; or

(2) The formula used to calculate the reimbursement as appropriated by the general assembly for products dispensed by pharmacies is changed resulting in lower reimbursement to the pharmacist in the aggregate than provided in fiscal year 2003; or

(3) September 30, 2015.

The director of the department of social services shall notify the revisor of statutes of the expiration date as provided in this subsection. The provisions of sections 338.500 to 338.550 shall not apply to pharmacies domiciled or headquartered outside this state which are engaged in prescription drug sales that are delivered directly to patients within this state via common carrier, mail or a carrier service.

2. Sections 338.500 to 338.550 shall expire on September 30, 2015.

(L. 2002 S.B. 1248, A.L. 2003 H.B. 286 merged with H.B. 600, A.L. 2005 S.B. 189, A.L. 2006 S.B. 822, A.L. 2007 S.B. 4, A.L. 2009 H.B. 395 merged with H.B. 740, A.L. 2011 S.B. 62)

Expires 9-30-15

**CROSS REFERENCE:**

*Nonseverability clause, 190.840*

**338.600. Criteria for audit--appeals process to be established--report to be provided--applicability exceptions.**

1. Notwithstanding any other provision of law to the contrary, when an audit of the records of a pharmacy licensed in this state is conducted by a managed care company, insurance company, third-party payor, or any entity that represents such companies or groups, such audit shall be conducted in accordance with the following:

(1) The entity conducting the initial on-site audit shall provide the pharmacy with notice at least one week prior to conducting the initial on-site audit for each audit cycle;

(2) Any audit which involves clinical judgment shall be conducted by or in consultation with a licensed pharmacist;

(3) Any clerical error, record-keeping error, typographical error, or scrivener's error regarding a required document or record shall not constitute fraud or grounds for recoupment, so long as the prescription was otherwise legally dispensed and the claim was otherwise materially correct; except that, such claims may be otherwise subject to recoupment of overpayments or payment of any discovered underpayment. No claim arising under this subdivision shall be subject to criminal penalties without proof of intent to commit fraud;

(4) A pharmacy may use the records of a hospital, physician, or other authorized practitioner of the healing arts involving drugs or medicinal supplies written or transmitted by any means of communication for purposes of validating the pharmacy record with respect to orders or refills of a legend or narcotic drug. Electronically stored images of prescriptions, electronically created annotations and other related supporting documentation shall be considered valid prescription records. Hard copy and electronic signature logs that indicate the delivery of pharmacy services

shall be considered valid proof of receipt of such services by a program enrollee;

(5) A finding of an overpayment or underpayment may be a projection based on the number of patients served and having a similar diagnosis or on the number of similar orders or refills for similar drugs; except that, recoupment of claims shall be based on the actual overpayment or underpayment unless the projection for overpayment or underpayment is part of a settlement as agreed to by the pharmacy;

(6) Each pharmacy shall be audited under the same standards and parameters as other pharmacies audited by the entity;

(7) A pharmacy shall be allowed at least thirty days following receipt of the preliminary audit report in which to produce documentation to address any discrepancy found during an audit;

(8) The period covered by the audit shall not exceed a two-year period beginning two years prior to the initial date of the on-site portion of the audit unless otherwise provided by contractual agreement or if there has been a previous finding of fraud or as otherwise provided by state or federal law;

(9) An audit shall not be initiated or scheduled during the first three business days of any month due to the high volume of prescriptions filled during such time unless otherwise consented to by the pharmacy;

(10) The preliminary audit report shall be delivered to the pharmacy within one hundred twenty days after conclusion of the audit, with reasonable extensions permitted. A final audit report shall be delivered to the pharmacy within six months of receipt by the pharmacy of the preliminary audit report or final appeal, as provided for in subsection 3 of this section, whichever is later;

(11) Notwithstanding any other provision in this subsection, the entity conducting the audit shall not use the accounting practice of extrapolation in calculating recoupments or penalties for audits, except as otherwise authorized under subdivision (5) of this subsection.

2. Recoupments of any disputed moneys shall only occur after final internal disposition of the audit, including the appeals process set forth in subsection 3 of this section. Should the identified discrepancy for an individual audit exceed twenty-five thousand dollars, future payments to the pharmacy in excess of twenty-five thousand dollars may be withheld pending finalization of the audit.

3. Each entity conducting an audit shall establish an appeals process, lasting no longer than six months, under which a licensed pharmacy may appeal an unfavorable preliminary audit report to the entity. If, following such appeal, the entity finds that an unfavorable audit report or any portion thereof is unsubstantiated, the entity shall dismiss the audit report or such portion without the necessity of any further proceedings.

4. Each entity conducting an audit shall provide a copy of the final audit report, after completion of any appeal process, to the plan sponsor.

5. This section shall not apply to any investigative audit that involves probable fraud, willful misrepresentation, or abuse.

6. This section shall not apply to any audit conducted as part of any inspection or investigation conducted by any governmental entity or law enforcement agency.

*(L. 2008 S.B. 1068)*

### **338.650. Fund established, use of moneys.**

There is hereby established in the state treasury the "Pharmacy Rebates Fund". Any revenues received by the state, either directly or indirectly, from pharmaceutical manufacturer rebates as required by federal law, except where federal law requires rebates to be accounted for otherwise, or state supplemental rebates as defined in state plan amendments shall be deposited into the pharmacy rebates fund and shall be used only in the MO HealthNet pharmacy program or its successor programs authorized under Title XIX, Public Law 89-97, 1965 amendments to the federal Social Security Act, 42 U.S.C. Section 301, et seq.

*(L. 2008 S.B. 1068)*

# **BOP REGULATIONS**

**DIVISION 2220  
STATE BOARD OF  
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20 CSR 2220-1



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Division 2220—State Board of Pharmacy  
Chapter 1—Organization and  
Description of Board**

**20 CSR 2220-1.010 General Organization**

*PURPOSE: The purpose of this regulation is to comply with section 536.023(3), RSMo (1986) which requires each agency to adopt as a regulation, a description of its operation and the methods and procedures where the public may obtain information or make submissions or requests.*

(1) The State Board of Pharmacy is a unit of the Division of Professional Registration of the Department of Economic Development.

(2) The board was created by House Bill No. 87 of the General Assembly of 1909.

(3) The State Board of Pharmacy shall consist of seven (7) persons not connected with any school of pharmacy. Annually the board shall organize by the election of a president and vice president each of whom serves for one (1) year. Six (6) members shall be licensed as pharmacists and actively engaged in the practice of pharmacy within this state and at least one (1) of these shall be a person who provides, on a full-time basis, pharmaceutical services to a hospital, skilled nursing facility or an intermediate care facility. The other member shall be a voting public member. All members shall be appointed by the governor, with the approval of the senate and shall hold their offices for five (5) years from the date of their appointments and until their successors shall have been appointed and qualified.

(4) The board is directed by sections 338.140, 338.280 and 338.350, RSMo to adopt rules for the application and enforcement of Chapter 338, RSMo which also requires compliance of Chapter 195, RSMo.

(5) The board has superintending control over the practice of pharmacy and drug distributors and its primary duties consist of—

- (A) Examining and licensing of applicants;
- (B) Assisting in the accrediting of pharmacy colleges and approval of their programs;
- (C) Renewing annually the license of qualified pharmacists, pharmacies, intern pharmacists and drug distributors;
- (D) Suspending, revoking, placing on probation or censure of licenses of any pharmacist, pharmacy, intern pharmacist or drug distributors found guilty of violating

the provisions set forth in Chapter 338, RSMo;

(E) Inspecting pharmacies and drug distributors;

(F) Inspecting and certification of pharmacies as intern-training pharmacies;

(G) Interacting and participating with various state and national organizations in order to facilitate the exchange of information, policies and procedures and techniques that can assist the board in fulfilling its mission; and

(H) Interacting with other state and federal agencies as concerns the enforcement of state and federal drug laws.

(6) "Open premises" as used in Chapter 338, RSMo means all premises accessible to employees in the regular course of any business which engages in practices regulated by this chapter, including, but not limited to, locked or otherwise secured storage areas that are used for the purpose of storing drugs, poisons, chemicals, or equipment used in any practice regulated by this chapter, and/or storage areas that are used for the purpose of storing records related to any practice regulated by this chapter.

(7) The public may obtain information from the board, or make submissions or requests to the board, by writing the executive director of the board. The information request shall be reviewed for appropriate action.

*AUTHORITY: sections 338.110, 338.140 and 338.280, RSMo 2000.\* This rule originally filed as 4 CSR 220-1.010. Original rule filed Dec. 31, 1975, effective Jan. 10, 1976. Amended: Filed April 14, 1982, effective July 11, 1982. Amended: Filed Jan. 3, 1990, effective May 11, 1990. Amended: Filed Aug. 25, 1996, effective April 30, 1996. Amended: Filed May 13, 2005, effective Oct. 30, 2005. Moved to 20 CSR 2220-1.010, effective Aug. 28, 2006.*

*\*Original authority 338.110, RSMo 1939, amended 1949, 1981, 1999; 338.140, RSMo 1939, amended 1981, 1989, 1997; 338.280, RSMo 1951, amended 1971, 1981.*

**20 CSR 2220-1.020 Board Compensation**

*PURPOSE: This rule fixes the compensation for the members of the State Board of Pharmacy in compliance with the mandates of section 338.130, RSMo (1986).*

(1) Each member of the State Board of Pharmacy shall receive as compensation the sum of fifty dollars (\$50) for each day that member devotes to the affairs of the board.

(2) In addition to the compensation fixed in this rule, each member is entitled to reimbursement of his/her expenses necessarily incurred in the discharge of his/her

official duties.

(3) No request for the compensation provided in this rule shall be processed for payment unless sufficient funds are available for that purpose within the appropriation for this board.

*AUTHORITY: sections 338.130 and 338.140, RSMo 1986.\* This rule originally filed as 4 CSR 220-1.020. Emergency rule filed Sept. 11, 1981, effective Sept. 28, 1981, expired Jan. 13, 1982. Original rule filed Sept. 11, 1981, effective Jan. 14, 1982. Moved to 20 CSR 2220-1.020, effective Aug. 28, 2006.*

*\*Original authority: 338.130, RSMo 1939, amended 1949, 1961, 1969, 1981, 1997; 338.140, RSMo 1939, amended 1981, 1989, 1997.*

20 CSR 2220-2



**Title 20—DEPARTMENT OF  
INSURANCE, FINANCIAL  
INSTITUTIONS AND  
PROFESSIONAL REGISTRATION  
Division 2220—State Board of Pharmacy  
Chapter 2—General Rules**

**20 CSR 2220-2.005 Definitions**

*PURPOSE: This rule defines the term “drug” as utilized in Chapter 338, RSMo, and the rules of the board.*

(1) “Drug,” “prescription drug,” or “legend drug” means any drug or biological product—

(A) Subject to section 503(b) of the Federal Food, Drug and Cosmetic Act, including finished dosage forms and active ingredients subject to section 503(b);

(B) Required by federal law to be labeled with one (1) of the following statements, prior to being dispensed or delivered:

1. “Caution: Federal law prohibits dispensing without prescription”;

2. “Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian”; or

3. “Rx Only”; and

(C) Required by any applicable federal or state law or regulation to be dispensed by prescription only or that is restricted to use by practitioners only.

(2) For purposes of sections 338.300 to 338.370, RSMo, the term “drug,” “prescription drug,” or “legend drug” shall not include:

(A) An investigational new drug or biological product, as defined by 21 CFR 312.3(b), that is being utilized for the purposes of conducting a clinical trial/investigation of that drug or product if such clinical trial/investigation is governed by, and being conducted pursuant to, 21 CFR 312, et seq.;

(B) A legend drug or biological product being utilized for the purposes of a clinical trial/investigation that is governed by, and being conducted pursuant to, 21 CFR 312, et seq.; or

(C) A legend drug or biological product being utilized for the purposes of a clinical trial/investigation that is governed or approved by an institutional review board subject to 21 CFR 56 or 45 CFR Part 46.

*AUTHORITY: section 338.010, RSMo Supp. 2010 and sections 338.140, 338.280, and 338.350, RSMo 2000.\* Emergency rule filed Sept. 3, 2010, effective Sept. 13, 2010, expired March 11, 2011. Original rule filed March 7, 2011, effective Aug. 30, 2011.*

*\*Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009; 338.140, RSMo 1939, amended 1981, 1989, 1997; 338.280, RSMo 1951, amended 1971, 1981; and 338.350, RSMo 1989,*

*amended 1993, 1995.*

**20 CSR 2220-2.010 Pharmacy Standards of Operation**

*PURPOSE: This rule defines terms used in the regulations of the State Board of Pharmacy and outlines the conditions necessary for the operation of a pharmacy.*

(1) The word medicine or medicines is a word similar or of like import to the words pharmacist, pharmacy, apothecary shop, chemist shop, drug store, druggist and drugs, and no person shall carry on, conduct or transact a business under a name which contains, as part of the name, the word medicine or medicines, unless the place of business is supervised by a licensed pharmacist.

(A) At all times when prescriptions are compounded in a pharmacy or other establishments holding a Missouri pharmacy permit, there shall be on duty and present in that place of business a pharmacist licensed in Missouri as provided by law. In any Class J: Shared Service pharmacy where a permit is maintained at a location for the purpose of remote dispensing as defined in 20 CSR 2220-2.900 the pharmacist may be considered on duty and present as long as all required electronic connection requirements are maintained and the pharmacist is accessible at all times to respond to patient’s or other health professionals’ inquiries or requests pertaining to drugs dispensed through the use of the automated pharmacy system. When there is no pharmacist on duty, no prescription will be compounded, dispensed or otherwise provided and the public will be advised that no pharmacist is on duty by means of signs stating this fact. The signs will be displayed prominently on the doors of all entrances and the prescription counter of the pharmacy and the signs will be composed of letters of a minimum height of two inches (2”).

(B) Whenever, in a pharmacy or other establishment holding a Missouri pharmacy permit, a person other than a licensed pharmacist does compound, dispense or in any way provide any drug, medicine or poison pursuant to a lawful prescription, a licensed pharmacist must be physically present within the confines of the dispensing area, able to render immediate assistance and able to determine and correct any errors in the compounding, preparation or labeling of that drug, medicine or poison before the drug, medicine or poison is dispensed or sold. In any Class J: Shared Service pharmacy where a permit is maintained at a location for the purpose of remote dispensing as defined in 20 CSR 2220-2.900 the pharmacist may be considered on duty and present as long as all required electronic connection requirements are maintained and the pharmacist is accessible at all times to respond to patient’s or other health professionals’ inquiries or requests pertaining to drugs dispensed through the use of the automated pharmacy system. The pharmacist personally shall inspect and verify the

accuracy of the contents of, and the label after it is affixed to, any prescribed drug, medicine or poison compounded or dispensed by a person other than a licensed pharmacist.

(C) No pharmacy shall be licensed under the provisions of this chapter unless it is equipped with proper pharmaceutical equipment and reference manuals. Requirements for proper equipment and references may vary between pharmacies and must insure accuracy and safety of all pharmaceutical activity.

1. Basic equipment recognized by the latest edition of the United States Pharmacopoeia (USP), the United States Pharmacopoeia/Drug Information (USP/DI) or Remington's Pharmaceutical Sciences shall be available for any procedures utilized in the dispensing, compounding or admixture of drugs and drug-related devices, and must maintain conformance with these publications.

2. A suitable machine or electronic data device for the numbering of all prescriptions must be maintained along with appropriate printing equipment for the production of prescription drug labels.

(D) Reference manuals may include any generally recognized pharmaceutical publication other than periodicals or journals. A pharmacy must maintain, at a minimum, the current or latest edition of a reference manual(s) which includes all Federal Drug Administration (FDA)-approved drugs. The following topics must be included in the reference(s) selected:

1. Pharmacology of drugs;
2. Dosages and clinical effects of drugs; and
3. Patient information.

(E) Pharmacies shall maintain at least one (1) current edition of statutes and rules governing the pharmacy's practice.

(F) All pharmacies shall be maintained in a clean and sanitary condition at all times. Any procedures used in the dispensing, compounding and admixture of drugs or drug-related devices must be completed under clean and, when recommended, aseptic conditions.

1. Appropriate sewage disposal and a hot and cold water supply within the pharmacy must be available.

2. Appropriate housekeeping and sanitation of all areas where drugs are stored or dispensed must be maintained.

3. Animals, except for service animals as defined by the Americans with Disabilities Act (ADA), are not allowed in pharmacies.

(G) The temperature of the facility where drugs are stored must be maintained thermostatically within temperature requirements as provided for by the manufacturer or the latest edition of the USP. Adequate refrigeration must be available to insure enough storage space for drugs requiring refrigeration or freezing and under temperatures adequate to maintain the drug products as recommended by the manufacturer, the latest edition of the USP, or both. Drugs and drug-related devices must

be stored separately from food and other items.

(H) Pharmacies must maintain adequate security in order to deter theft of drugs by personnel or the public. Sufficient alarm systems or locking mechanisms must be in place if the pharmacy is located in a facility into which the public has access and the pharmacy's hours of operation are different from those of the remainder of the facility.

(I) Pharmacies which maintain storage sites or warehouse facilities for the storage of pharmaceuticals at a separate address or premises from the main pharmacy that holds a pharmacy permit shall register those sites as storage facilities of the licensed pharmacy. Information required for proper registration of a storage facility shall include the address of the facility, hours of operation (if applicable), pharmacy permit numbers of the pharmacies that it services, and a certified statement that the facility is used for the sole purpose of distributing drugs only within its own pharmacy operations.

1. Records must be maintained at these facilities to guarantee security, storage and accountability of all drugs and drug-related devices under proper conditions.

2. All storage and warehouse locations will be considered facilities of a pharmacy pursuant to section 338.240, RSMo and shall be subject to inspection by the board as defined in section 338.150, RSMo.

3. No fee will be charged by the board for registering a facility as defined in subsection (1)(I) of this rule.

(J) Pharmacies that maintain storage sites or warehouse facilities for the storage of confidential pharmacy records at a separate address or premises from the main pharmacy that holds a pharmacy permit shall register those sites as storage facilities of the licensed pharmacy. Information required for proper registration of a storage facility shall include the address of the facility, hours of operation (if applicable), pharmacy permit numbers of the pharmacies that it services, and a statement that the facility is used for the sole purpose of storing records within its own pharmacy operations.

1. All storage and warehouse locations must maintain adequate security including an alarm system. Any breach in security must be documented and reported in writing via facsimile, email communication, or letter to the board within fifteen (15) days of the breach of confidentiality.

2. All storage and warehouse locations will be considered facilities of a pharmacy pursuant to section 338.240, RSMo and shall be subject to inspection by the board as defined in section 338.150, RSMo.

3. No fee will be charged by the board for registering a facility as defined in subsection (1)(J) of this rule.

4. All storage and warehouse locations must comply with 19 CSR 30-1.

5. No records less than two (2) years old may be stored offsite.

6. All storage and warehouse locations storing confidential pharmacy records must make records retriev-



able within two (2) business days when requested by the board or its representatives.

(K) All pharmacists will be required to have a photo of themselves not smaller than two inches by two inches (2" x 2") in the upper right-hand corner of the current renewal licenses. This photo and license renewal shall be conspicuously exposed in the pharmacy or drug store or place of business in which the pharmacist is employed as required by law.

(L) Pharmacists regularly working as relief persons for more than one (1) store shall have in their possession proper identification of their pharmacy licensure.

(M) Pharmacy operations must be conducted at all times under the supervision of a properly designated pharmacist-in-charge. When a licensed pharmacist leaves the employment of a pharmacy where s/he has been pharmacist-in-charge, s/he immediately shall notify the executive director of the board of the termination of his/her services in the pharmacy. Likewise, the holder of the permit shall notify the executive director of the board of the termination of the services and give the name of the new licensed pharmacist-in-charge.

(N) Pharmacists are responsible to inform the executive director of the board in the case of changed address. Any mail or communications returned to the executive director's office marked Unknown, Incorrect Address, and the like, will not be sent out a second time until the correct address is sent in.

(O) When a pharmacy permit holder knows or should have known, within the usual and customary standards of conduct governing the operation of a pharmacy as defined in Chapter 338, RSMo, that an employee, licensed or unlicensed, has violated the pharmacy laws or rules, the permit holder shall be subject to discipline under Chapter 338, RSMo.

(P) When required by section 338.013(10), RSMo, to report technician disciplinary action, the pharmacy must notify the board in writing within fifteen (15) days of the action. The notification must include:

1. The name and permit number of pharmacy;
2. Name of person making the notification;
3. Name of technician;
4. Technician registration number;
5. Date of action; and
6. Reason for action.

(Q) Pharmacists must inform the executive director of the board of any change in their employment address. The notification of an employment change must be provided in writing to the board no later than fifteen (15) days following any effective change.

(2) Every pharmacy shall designate as its primary means of record keeping either a manual system which provides for the consecutive numbering of hard copy prescriptions and complies with the provisions of section (3) of this rule or an electronic system which complies with the provisions of 20 CSR 2220-2.080. The designated

record system shall be used to record the pharmacy's dispensing of all drugs, medicines and poisons.

(3) A pharmacy using a record keeping system other than an electronic system meeting the requirements of 20 CSR 2220-2.080 to record its dispensing of drugs, medicines and poisons shall provide a method of recording all of the following information concerning the refill of any prescription medication on the back or reverse side of every prescription order:

(A) The date the drug, medicine or poison was dispensed;

(B) The dispensing pharmacist's initials; and

(C) The amount of drug, medicine or poison dispensed to the patient if different from the amount on the face of the prescription order.

(4) Each licensed pharmacy shall maintain at least three (3) separate files of prescriptions and they shall be as follows:

(A) All prescriptions for controlled drugs listed in Schedules I and II shall be maintained in a separate prescription file;

(B) All prescriptions for controlled drugs listed in Schedules III, IV and V shall be maintained in a separate prescription file; and

(C) All other prescriptions for noncontrolled drugs shall be maintained in a separate prescription file(s).

(5) Pharmacies shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of legend drugs. Said records shall be maintained for two (2) years and be readily retrievable upon request by the board or its representatives.

(6) Drugs and devices that are maintained as part of the pharmacy inventory or are being processed for dispensing or other distribution purposes must be physically separated at all times from articles, supplies or other drugs that are for employee personal use or that are outdated, distressed, misbranded or adulterated. An area separate from drug storage must be used to store quarantined, nonusable substances. Areas used for this type of drug storage must be clearly identified. Any prescription drugs that are present in a licensed pharmacy but are for the personal use of pharmacy personnel must be labeled in accordance with section 338.059, RSMo.

(7) All records required by Chapters 195 and 338, RSMo or divisions 20 CSR 2220 and 19 CSR 30 shall be available for photocopying or electronic duplication by a board of pharmacy representative.

(8) Except as provided for in section 21 U.S.C. section 353(d)(1)(A)-(C), (d)(2)(A)(i)-(ii), (d)(2)(B)(i)-(iv), and (d)(3)(A)(i)-(ii) of the Federal Food, Drug and Cosmetic

Act, drug samples shall not be maintained in pharmacies.

(9) A home health or hospice agency licensed or certified according to Chapter 197, RSMo, or any licensed nurses of such agency, may possess drugs in the usual course of business of such agency without being licensed as a pharmacist or a pharmacy.

(A) The list of drugs that may be possessed by a home health or hospice agency without a license or permit, as defined in section (9), is as follows:

1. Injectable dosage forms of sodium chloride and water;
2. Irrigation dosage forms of sodium chloride and water that carry a federal prescription only restriction;
3. Injectable dosage forms of heparin and alteplase in concentrations that are indicated for maintenance of venous access devices;
4. Injectable dosage forms of diphenhydramine and epinephrine;
5. Vaccines indicated for public health needs, such as influenza, pneumonia, hepatitis A and hepatitis B; and
6. Tuberculin test material.

(B) The agency shall have a policy and procedure that addresses at least the following:

1. Specific drugs authorized to be possessed by the agency and the nurse;
2. Indications for use of the drugs possessed;
3. Receiving physicians' orders for administration of the drugs;
4. Leaving drugs with the patient for routine care procedures;
5. Conditions for storage and transport of the drugs by the agency and the nurse; and
6. Quantity of drugs possessed by the agency and the nurse.

(C) The nurse must have a physician's authorization, such as an individual patient order, protocol or standing order, to administer the drugs.

(D) When the patient or the patient's representative has been instructed, verbally and in writing, in the performance of routine care procedures, up to a two (2)-week supply of sodium chloride, water, and heparin may be left with the patient for these procedures. Drugs left with the patient shall be labeled with instructions for use. A record shall be made of all drugs left with the patient in the patient's medical record. Drugs left with the patient may not be returned to the agency.

(E) Drugs may be stored at the agency or transported by the nurse, and shall be stored or transported at all times in accordance with the manufacturer's storage requirements. Refrigerator units used by the agency for storing drugs shall not be used for storing non-drug items.

(F) All drugs must be received from a licensed pharmacy or drug distributor. The quantity of drugs possessed by an agency shall be limited to that necessary to meet

the needs of the agency's patient population for two (2) weeks.

(10) Class I: Consultant Pharmacies as defined in 20 CSR 2220-2.020(9)(I) and approved by the board to be located within a residence shall be required to address and comply with the following minimum standards of practice:

(A) Location Requirements—

1. The pharmacy must be located in a separate room that provides for a door with suitable lock;
2. Sufficient storage for securing confidential documents and any hardware used in accessing a central pharmacy by electronic connection must be provided;
3. Ceiling and walls must be constructed of plaster, drywall, brick or other substantial substance that affords a design that makes the room separate and distinct from the remainder of the domicile. Drop down ceilings that allow access into the room are not allowed;
4. All locations must be inspected and have approval by the board prior to the initiation of services; and
5. Patients are not allowed in the pharmacy.

(B) Documentation—

1. Maintain a current policy and procedure manual that is attested by the signature and date of review of the pharmacist-in-charge to its accuracy. All pharmacists working at the pharmacy shall be required to sign the manual attesting to their review and understanding of all policies and procedures in force;
2. Maintain documentation that the permit holder has provided training to all personnel on all operations associated with the pharmacy;
3. The permit holder must complete an audit to ensure compliance with pharmacy policy and procedures and this regulation at a minimum of twice per year, through physical visits by representatives of the permit holder. Audit results must be maintained by the permit holder for a period of three (3) years; and
4. If the pharmacist is working under a contract for the permit holder, a copy of the contract shall be available during an inspection.

(C) Security—Records and Internet—

1. All electronic data processing systems must meet all applicable state and federal confidentiality laws and regulations;
2. Data processing systems must utilize sufficient security software;
3. Any breach in the security of the system must be documented and reported to the board of pharmacy within seven (7) days of the breach of confidentiality. Such documentation shall be available during an inspection.

(D) Licensure and Inspection—

1. Each location must maintain and display a current Class I permit. The permit holder for this permit must be the pharmacy the individual pharmacist is employed by or contracted with;

2. Routine inspections for in-state pharmacies shall be arranged ahead of time. Notification by the inspector to the permit holder will be provided a minimum of seventy-two (72) hours ahead of the scheduled inspection. The permit holder must arrange for a designated representative to be present that is not a resident of the location under inspection;

3. A pharmacy located outside the state must maintain a pharmacist-in-charge with a current and active pharmacist license with the state of Missouri;

4. The audits required in paragraph (10)(B)3. shall be available for review during the inspection; and

5. The pharmacy shall provide copies of inspections completed by the state in which they are located if such inspections are required within seven (7) business days of the inspection date.

*AUTHORITY: sections 338.140, 338.240, and 338.280, RSMo 2000 and sections 338.010 and 338.210, RSMo Supp. 2007.\* This rule originally filed as 4 CSR 220-2.010. Original rule filed July 18, 1962, effective July 28, 1962. Amended: Filed Nov. 9, 1966, effective Nov. 19, 1966. Amended: Filed Oct. 27, 1970, effective Nov. 6, 1970. Amended: Filed Dec. 31, 1975, effective Jan. 10, 1976. Amended: Filed May 21, 1979, effective Nov. 12, 1979. Amended: Filed April 14, 1982, effective July 11, 1982. Amended: Filed April 16, 1985, effective Sept. 27, 1985. Amended: Filed Nov. 4, 1985, effective March 13, 1986. Amended: Filed Dec. 15, 1987, effective April 28, 1988. Amended: Filed Oct. 12, 1988, effective March 11, 1989. Amended: Filed Jan. 30, 1991, effective July 8, 1991. Amended: Filed Jan. 27, 1995, effective Sept. 30, 1995. Amended: Filed June 29, 1999, effective Jan. 30, 2000. Amended: Filed March 15, 2000, effective Sept. 30, 2000. Amended: Filed July 24, 2001, effective Feb. 28, 2002. Amended: Filed Feb. 18, 2003, effective Sept. 30, 2003. Amended: Filed May 13, 2005, effective Oct. 30, 2005. Moved to 20 CSR 2220-2.010, effective Aug. 28, 2006. Amended: Filed Aug. 21, 2006, effective April 30, 2007. Amended: Filed Feb. 6, 2008, effective Aug. 30, 2008.*

*\*Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007; 338.140, RSMo 1939, amended 1981, 1989, 1997; 338.210, RSMo 1951, amended 2001; 338.240, RSMo 1951; and 338.280, RSMo 1951, amended 1971, 1981.*

## **20 CSR 2220-2.013 Prescription Delivery Requirements**

*PURPOSE: This rule establishes requirements for authorized prescription delivery sites.*

(1) Every pharmacy delivering prescription drugs shall develop and implement written policies and procedures to ensure the safe and appropriate delivery of prescrip-

tion drugs within the temperature requirements recommended by the manufacturer or the United States Pharmacopeia (USP). Except as otherwise provided herein, prescriptions filled by a Missouri licensed pharmacy may not be left at, accepted by, or delivered to a location, place of business or entity not licensed as a pharmacy.

(2) At the request of the patient or the patient's authorized designee, licensees may deliver a filled prescription for an individual patient directly to the patient or the patient's authorized designee or to—

(A) The office of a licensed health care practitioner authorized to prescribe medication in the state of Missouri;

(B) A long-term care facility as defined by 20 CSR 2220-2.140 where the patient resides;

(C) A hospital, office, clinic, or other medical institution that provides health care services;

(D) A residence designated by the patient or the patient's authorized designee; or

(E) The patient's office or place of employment.

(3) At the request of a customer, legally filled prescriptions for veterinary use may be delivered to a residence, business, or clinic designated by the customer.

(4) Licensees shall comply with all applicable controlled substance laws and regulations, including, but not limited to, all applicable security requirements.

(5) Returns of medication delivered pursuant to this section shall be governed by, and handled in accordance with, Chapter 338, RSMo, and the rules of the board.

*AUTHORITY: section 338.280, RSMo 2000, and sections 338.095, 338.100, 338.140, and 338.240, RSMo Supp. 2011.\* Original rule filed May 14, 2012, effective Nov. 30, 2012.*

*\*Original authority: 338.095, RSMo 1993, amended 2007; 338.100, RSMo 1939, amended 1971, 1990, 1997, 1999, 2010; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; 338.240, RSMo 1951, amended 2011; and 338.280, RSMo 1951, amended 1971, 1981.*

## **20 CSR 2220-2.015 Termination of Business as a Pharmacy**

*PURPOSE: This rule establishes guidelines for the termination of business as a pharmacy.*

(1) A licensed pharmacy who plans to terminate business activities shall file a written notice with the State Board of Pharmacy. The written notice shall be submitted to the State Board of Pharmacy in person or by registered or certified mail within fifteen (15) days after the date of termination. This notice shall be made on a form provided by the board or in letter form from the licensee

and shall include the following information:

(A) The name, address, license (permit) number and effective date of closing;

(B) The name, address, and license (permit) number of the entity to which any of the stock/inventory will be transferred;

(C) The name and address of the location to which records, required to be maintained by law, have been transferred.

1. Any records that are transferred to an unlicensed location must be retrievable for board review within seven (7) working days of a request made by an authorized official of the board.

2. Any records that are transferred to a licensed (permitted) pharmacy or licensed drug distributor must be maintained in accordance with record requirements as set forth in section 338.100, RSMo.

(2) The licensee (permit holder) terminating business may transfer all drugs and records in accordance with the following:

(A) On the date of termination, a complete inventory of all controlled substances being transferred or disposed of shall be completed according to state and federal laws. This inventory shall serve as the final inventory of the pharmacy terminating business and as the initial inventory of the licensed entity to which the controlled substances are being transferred. A copy of the inventory shall be included in the records of each licensee or permit holder involved in the transfer.

(B) A pharmacy terminating business shall not transfer misbranded, outdated or adulterated drugs, except for purposes of proper disposal; and

(C) Upon the actual termination of business, the license (permit) of the pharmacy shall be returned to the State Board of Pharmacy for cancellation either in person or by registered or certified mail.

(3) A one (1)-time transfer of drugs and devices due to a termination of business that is in compliance with this rule will not require a pharmacy to seek licensure as a drug distributor under sections 338.330 and 338.333, RSMo.

(4) The requirements of this rule are not intended to replace or be in conflict with any other laws or regulations governing the appropriate licensure, change of ownership or change of location of a pharmacy.

(5) The termination date is the date on which the permit holder ceases to practice pharmacy as defined in sections 338.010 and 338.210, RSMo, at the permitted location.

**AUTHORITY:** sections 338.210 and 338.280, RSMo 1994. \* This rule originally filed as 4 CSR 220-2.015. Original rule filed May 4, 1995, effective Dec. 30, 1995. Moved to 20 CSR 220-2.015, effective Aug. 28, 2006.

*\*Original authority: 338.210, RSMo 1951 and 338.280, RSMo 1951, amended 1971, 1981.*

## **20 CSR 220-2.016 Pharmacy Operating Procedures During Declared Disasters**

**PURPOSE:** This rule is to establish guide-lines for the operation and temporary relocation of a pharmacy during a declared disaster.

(1) Declared disaster areas are defined as specified geographical counties within the state that have been designated by the governor or federal authorities as counties that have been adversely affected by a natural or man-made disaster and requires extraordinary measures to provide adequate, safe and effective health care for the affected population.

(2) In cases where a disaster as defined in section (1) has been declared, any pharmacy located within the disaster area may arrange to move to a temporary location to better serve the public or provide pharmacy services from a mobile unit that is under the control and management of the pharmacist-in-charge.

(A) The following constitutes requirements for maintaining temporary or mobile facilities:

1. Temporary or mobile pharmacy facilities shall only be located within the disaster area or adjacent county;

2. Temporary facilities may be maintained by a pharmacy operation for a period of up to six (6) months without applying for a change of location. Any pharmacy wishing to maintain a temporary site for more than six (6) months or desires to remain permanently at the temporary site, must apply for a change of location as outlined in 4 CSR 220-2.020(4);

3. Mobile pharmacy operations must cease services once the immediate disaster is over;

4. Temporary or mobile pharmacy facilities must inform the board of their location and provide an estimate of the time period for which the temporary or mobile pharmacy operation will be needed; and

5. The executive director shall have the authority to approve or disapprove temporary or mobile pharmacy facilities and shall make arrangements for appropriate monitoring and inspection of the pharmacy on a case by case basis.

A. Approval of this type of operation will be based on the need, type and scope of disaster, as well as the ability of the pharmacy to comply with state and federal drug laws in addition to section 338.240, RSMo.

B. Temporary or mobile pharmacy facilities shall cease operations under the provisions of this rule if any previous approval is withdrawn.

C. Any decision made concerning the approval of a temporary or mobile pharmacy shall not interfere with any rights or privileges of a pharmacy permit holder at the original location of operation or prevent a permit holder from applying for a change of location as outlined

in 4 CSR 220-2.020(4).

**AUTHORITY:** sections 338.210 and 338.280, RSMo 1994.\* This rule originally filed as 4 CSR 220-2.016. Original rule filed May 4, 1995, effective Dec. 30, 1995. Moved to 20 CSR 2220-2.016, effective Aug. 28, 2006.

\*Original authority: 338.210, RSMo 1951 and 338.280, RSMo 1951, amended 1971, 1981.

## **20 CSR 2220-2.018 Prescription Requirements**

**PURPOSE:** This rule establishes requirements for information required on prescriptions.

(1) In order for a prescription to be valid for purposes of dispensing a medication by a pharmacy, it must conform to all requirements as outlined in sections 338.056 or 338.196, RSMo, and contain the following information:

- (A) The prescription date and a unique, readily retrievable identifier;
- (B) The name of the patient(s);
- (C) The prescriber's name, if an oral prescription, signature if a written prescription;
- (D) Any prescriber indication of name and dosage of drug, directions for use, name and dosage of drug dispensed;
- (E) The number of refills, when applicable;
- (F) The quantity dispensed in weight, volume or number of units;
- (G) The initials or name of the pharmacist responsible for processes in dispensing or compounding of the prescription;
- (H) Any change or alteration made to the prescription dispensed based on contact with the prescriber to show a clear audit trail. This shall include, but is not limited to, a change in quantity, directions, number of refills or authority to substitute a drug;
- (I) The address of the prescriber and the patient when the prescription is for a controlled substance;
- (J) The prescriber's Drug Enforcement Administration (DEA) number when the prescription is for a controlled substance; and
- (K) Any prescription, when it is for a controlled substance, must comply with all requirements of federal and state controlled substance laws.

(2) The information specified in section (1) shall be required and recorded on all handwritten, telephone, oral and electronically produced prescriptions that are processed for dispensing by a pharmacist/pharmacy.

**AUTHORITY:** sections 338.095, 338.100, 338.140, 338.240 and 338.280, RSMo 2000.\* This rule originally filed as 4 CSR 220-2.018. Original rule filed May 4, 1995, effective Dec. 30, 1995. Amended: Filed March 15, 2000, effective Sept. 30, 2000. Amended: Filed Nov.

1, 2000, effective June 30, 2001. Moved to 20 CSR 2220-2.018, effective Aug. 28, 2006.

\*Original authority: 338.095, RSMo 1939; 338.100, RSMo 1939, amended 1971, 1990, 1997, 1999; 338.140, RSMo 1939; amended 1981, 1989, 1997; 338.240, RSMo 1951; and 338.280, RSMo 1951, amended 1971, 1981.

## **20 CSR 2220-2.020 Pharmacy Permits**

**PURPOSE:** This rule outlines the requirements for obtaining and maintaining a pharmacy permit.

(1) All permits for the operation of a pharmacy shall expire on the date specified by the director of the Division of Professional Registration pursuant to 4 CSR 230-2.031.

(2) A pharmacy permit may be issued on the application of the owners. If the owner is a corporation, an officer of the corporation must sign the application as the applicant. If the owner is a partnership, a partner must sign the application as the applicant. If the owner is a limited liability partnership, a general partner must sign the application as the applicant. If the owner is a limited liability company, a member must sign the application as the applicant. In the case where a pharmacy is owned and operated by a person(s) who is a licensed pharmacist and in active charge of the pharmacy, the application for permit can be made by either party.

(A) An application for a pharmacy permit will become null and void if the applicant fails to complete the process for licensure within six (6) months of receipt of the application by the board.

(3) When a pharmacy changes ownership, the original permit becomes void on the effective date of the change of ownership. Before any new business entity resulting from the change opens a pharmacy for business, it must obtain a new permit from the board. A temporary license shall be issued once a completed application and fee have been received by the board. The effective date of the temporary license shall be the date the change of ownership is listed as effective on the application. Such license shall remain in effect until a permanent license is issued or denied by the board.

(A) A change of ownership of a pharmacy owned by a sole proprietor is deemed to have occurred when—

- 1. The business is sold and the sale becomes final;
- 2. The proprietor enters into a partnership with another individual or business entity; or
- 3. The proprietor dies; provided, however, that the proprietor's estate may continue to operate the pharmacy under the licensed pharmacist in good standing in this state, but in no case for a period of more than one (1) year and only so long as appropriate pharmacy permit

fees are paid.

(B) If a corporation owns a pharmacy, it is not necessary to obtain a new license if the owners of the stock change. If a limited liability partnership or a limited liability company owns a pharmacy, it is not necessary to obtain a new license if the partners or members of the company change, as long as the partnership or company is not dissolved by that change. It is necessary to file written notice with the State Board of Pharmacy within ten (10) days after a change occurs in partners in a limited liability partnership, or in members in a limited liability company. This notification must be in writing and certified. However, when a corporation, limited liability partnership, or limited liability company begins ownership of a pharmacy or transfers ownership of a pharmacy, a new license must be obtained regardless of the relationship between the previous and subsequent owners.

(C) All individuals or business entities owning twenty-five percent (25%) or more of the ownership of any entity owning a pharmacy must notify the board within thirty (30) days of acquiring the percentage.

(4) If an individual or business entity operating a pharmacy changes the location of the pharmacy to a new facility (structure), the pharmacy shall not open for business at the new location until the board or its duly authorized agent has inspected the premises of the new location and approved it and the pharmacy as being in compliance with section 338.240, RSMo and all other provisions of the law. Upon the approval and receipt of a change of location fee, the board shall issue a permit authorizing operation of a pharmacy at the new location and the permit shall bear the same number as the previous pharmacy permit. However, the permit remains valid if the pharmacy address changes, but not the location and an amended permit will be issued without charge under these circumstances.

(A) Remodeling of a licensed pharmacy within an existing structure shall be deemed to have occurred when any change in the storage conditions of the Schedule II controlled substances is made or new connections to water/sewer resources are made or any changes in the overall physical security of drugs stored in the pharmacy as defined in 4 CSR 220-2.010(1)(H) are made. Remodeling as defined within this section will not require the initiation of any change of location procedures. Satisfactory evidence of plans for any remodeling of a pharmacy must be provided to the board office thirty (30) days in advance of commencing such changes along with an affidavit showing any changes to the pharmacy physical plant and the projected completion date for any remodeling.

(5) Permits, when issued, will bear an original number. Permits must be posted in a conspicuous place in the pharmacy to which it is issued.

(6) No pharmacy permit will be issued unless the pharmacy area is under the direct supervision of a licensed pharmacist in good standing with the Missouri State Board of Pharmacy, who meets the requirements of 4 CSR 220-2.090.

(7) If the owner/applicant is not the licensed pharmacist-in-charge, then the pharmacist-in-charge must meet the requirements of 4 CSR 220-2.090 and complete the pharmacist-in-charge affidavit of the permit application and have it notarized.

(8) The names of all pharmacists regularly working in a pharmacy shall be clearly displayed on the premises of every establishment having a pharmacy permit.

(9) The following classes of pharmacy permits or licenses are hereby established:

(A) Class A: Community/Ambulatory. A pharmacy that provides services as defined in section 338.010, RSMo to the general public;

(B) Class B: Hospital Outpatient Pharmacy. A pharmacy operated by and located within a hospital that provides services as defined in section 338.010, RSMo to patients other than to the hospital's inpatient population;

(C) Class C: Long-Term Care. A pharmacy that provides services as defined in section 338.010, RSMo by the dispensing of drugs and devices to patients residing within long-term care facilities. A long-term care facility means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients;

(D) Class D: Non-Sterile Compounding. A pharmacy that provides services as defined in section 338.010, RSMo and provides a non-sterile compounded product as defined in 20 CSR 2220-2.400(1) and meets the following criteria:

1. Any product made from any bulk active ingredient in a batch quantity as defined in 20 CSR 2220-2.400(3).

(E) Class E: Radiopharmaceutical. A pharmacy that is not open to the general public and provides services as defined in section 338.010, RSMo limited to the preparation and dispensing of radioactive drugs as defined by the Food and Drug Administration (FDA) to health care providers for use in the treatment or diagnosis of disease and that maintains a qualified nuclear pharmacist as the pharmacist-in-charge;

(F) Class F: Renal Dialysis. A pharmacy that is not open to the general public that provides services as defined in section 338.010, RSMo limited to the dispensing of renal dialysis solutions and other drugs and devices associated with dialysis care;

(G) Class G: Medical Gas. A pharmacy that provides services as defined in section

338.010, RSMo through the provision of oxygen and other prescription gases for therapeutic uses;

(H) Class H: Sterile Product Compounding. A pharma-

cy that provides services as defined in section 338.010, RSMo and provides a sterile pharmaceutical as defined in 20 CSR 2220-2.200(11)(I) and (AA). Pharmacies providing sterile pharmaceuticals within the exemptions outlined in 20 CSR 2220-2.200(25) shall not be considered a Class H pharmacy;

(I) Class I: Consultant. A location where any activity defined in section 338.010, RSMo is conducted, but which does not include the procurement, storage, possession or ownership of any drugs from the location;

(J) Class J: Shared Service. A pharmacy that provides services as defined in section 338.010, RSMo, and is involved in the processing of a request from another pharmacy to fill or refill a prescription drug order, or that performs or assists in the performance of functions associated with the dispensing process, drug utilization review (DUR), claims adjudication, refill authorizations and therapeutic interventions; and

(K) Class K: Internet. A pharmacy that provides services as defined in section 338.010, RSMo, and is involved in the receipt, review, preparation, compounding, dispensing or offering for sale any drugs, chemicals, medicines or poisons for any new prescriptions originating from the Internet for greater than ninety percent (90%) of the total new prescription volume on any day. A prescription must be provided by a practitioner licensed in the United States authorized by law to prescribe drugs and who has performed a sufficient physical examination and clinical assessment of the patient.

(10) Pharmacy applications for initial licensure or renewals of a license shall accurately note each class of pharmacy that is practiced at the location noted on the application or renewal thereof. The permit (license) issued by the board shall list each class of licensure that the pharmacy is approved to engage in. Whenever a change in service classification occurs at a pharmacy the permit must be sent to the board with a notarized statement explaining any additions or deletions of pharmacy classes that are to be made.

(11) Prescriptions processed by any classification of licensed pharmacy must be provided by a practitioner licensed in the United States authorized by law to prescribe drugs and who has performed a sufficient physical examination and clinical assessment of the patient. A pharmacist shall not dispense a prescription drug if the pharmacist has knowledge, or reasonably should know under the circumstances, that the prescription order for such drug was issued on the basis of an Internet-based questionnaire, an Internet-based consultation, or a telephonic consultation, all without a valid preexisting patient-practitioner relationship.

**AUTHORITY:** sections 338.140 and 338.280, RSMo 2000.\* This rule originally filed as 4 CSR 220-2.020. Original rule filed July 18, 1962, effective July 28, 1962.

*Amended: Filed Nov. 9, 1966, effective Nov. 19, 1966. Amended: Filed Oct. 27, 1970, effective Nov. 6, 1970. Amended: Filed Dec. 31, 1975, effective Jan. 10, 1976. Emergency amendment filed July 15, 1981, effective Sept. 28, 1981, expired Nov. 11, 1981. Amended: Filed Aug. 10, 1981, effective Nov. 12, 1981. Amended: Filed April 14, 1982, effective July 11, 1982. Amended: Filed March 14, 1983, effective June 11, 1983. Amended: Filed Feb. 11, 1985, effective May 11, 1985. Amended: Filed Dec. 16, 1985, effective May 11, 1986. Amended: Filed Aug. 1, 1986, effective Nov. 13, 1986. Amended: Filed Jan. 27, 1995, effective Sept. 30, 1995. Amended: Filed Jan. 6, 1998, effective Aug. 30, 1998. Amended: Filed June 29, 1999, effective Jan. 30, 2000. Amended: Filed March 15, 2000, effective Sept. 30, 2000. Amended: Filed Nov. 30, 2001, effective June 30, 2002. Amended: Filed Dec. 3, 2002, effective June 30, 2003. Amended: Filed May 13, 2005, effective Oct. 30, 2005. Moved to 20 CSR 2220-2.020, effective Aug. 28, 2006. Amended: Filed Aug. 21, 2006, effective April 30, 2007.*

*\*Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997 and 338.280, RSMo 1951, amended 1971, 1981.*

## **20 CSR 2220-2.025 Nonresident Pharmacies**

**PURPOSE:** This rule establishes licensure guidelines for nonresident pharmacies.

(1) Nonresident pharmacies shall not ship, mail or deliver prescription drugs into Missouri without first obtaining a pharmacy license from the Missouri Board of Pharmacy. An exemption to licensure is allowed when a nonresident pharmacy provides a prescription drug in an emergency situation or supplies lawful refills to a patient from a prescription that was originally filled and delivered to a patient within the state in which the nonresident pharmacy is located or provides medications upon receipt of a prescription or physician order for patients in institutional settings and the nonresident pharmacy is not recognized as a primary provider.

(2) To obtain a license as a pharmacy, a nonresident pharmacy must comply with each of the following:

(A) Maintain a license in good standing from the state in which the nonresident pharmacy is located;

(B) Submit an application as provided by the Missouri Board of Pharmacy for licensure in compliance with 4 CSR 220-2.020(2) and (3);

(C) Pay all appropriate licensing fees;

(D) Submit a copy of the state pharmacy license from the state in which the nonresident pharmacy is located; and

(E) Submit a copy of the state and federal controlled substance registrations from the state in which it is located, if controlled substances are to be shipped into

Missouri.

(3) When requested to do so by the Missouri Board of Pharmacy, each nonresident pharmacy shall supply any inspection reports, warning notices, notice of deficiency reports or any other related reports from the state in which it is located concerning the operation of a nonresident pharmacy for review of compliance with state and federal drug laws.

(4) The Missouri Board of Pharmacy will extend reciprocal cooperation to any state that licenses and regulates nonresident pharmacies for the purpose of investigating complaints against pharmacies located in Missouri or the sharing of information and investigative reports, as long as the other state will extend the same reciprocal cooperation to the Missouri Board of Pharmacy.

*AUTHORITY: sections 338.140 and 338.280, RSMo 2000 and 338.220, RSMo Supp. 2001.\* This rule originally filed as 4 CSR 220-2.025. Original rule filed Jan. 16, 1990, effective May 11, 1990. Amended: Filed June 28, 2002, effective Jan. 30, 2003. Moved to 20 CSR 2220-2.025, effective Aug. 28, 2006.*

*\*Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997; 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997, 1999, 2001; and 338.280, RSMo 1951, amended 1971, 1981.*

## **20 CSR 2220-2.030 Educational and Licensing Requirements**

*PURPOSE: This rule outlines requirements for internship standards and training, exam scoring procedures, procedures for examination score transfer and licensure transfer and defines accredited colleges.*

(1) An approved school or college of pharmacy means a school or college of pharmacy whose curriculum, physical equipment, course of instruction and teaching personnel conform to the standards and specifications or the equivalent required by the American Council on Pharmaceutical Education for accreditation and is approved annually by the board.

(2) Application shall be made on forms provided by the State Board of Pharmacy. The candidate shall furnish satisfactory evidence on the application that s/he has graduated from an approved school of pharmacy and present affidavits certifying the completion of all practical experience programs that are required and are approved by the board. An application will be considered filed even though it may have to be returned to the applicant for minor correction or completion. However, an application will not be considered filed if it has to be returned to the applicant for any one (1) or more of the

following reasons:

(A) Incorrect or missing fee;

(B) Incomplete or missing college affidavit; or

(C) Incomplete or missing signature and notarization. In this instance, the application will be returned to the applicant and will not be considered filed until it has been returned with all corrections made. The applicant must take the examination(s) within three hundred sixty-five (365) days of having been determined eligible, to avoid forfeiture of eligibility and fees.

(3) Requirements for Practical Experience.

(A) Advanced practice experience is defined as practice based training which is documented as required, complies with training standards outlined in this rule and is considered a part of the school curriculum for training students within standards approved by the board of pharmacy.

(B) Requirements for Training as a Pharmacy Intern.

1. Every person who desires to gain practical experience in Missouri toward licensure as a pharmacist must apply for a license as an intern pharmacist. An application for licensure shall be made on forms provided by the State Board of Pharmacy and must be accompanied by the appropriate licensure fee. An application for an intern pharmacist license will become null and void if the applicant fails to complete the process for licensure within six (6) months of receipt of the application by the board.

2. An applicant for licensure as a pharmacy intern shall be currently enrolled in or graduated from a college that is approved by the State Board of Pharmacy and that applicant may apply for licensure after the completion of thirty (30) hours of college course work in an approved school of pharmacy.

3. Advanced practice experience hours shall include a minimum of one hundred sixty (160) hours in a community/ambulatory pharmacy practice component, an institutional pharmacy practice component and a clinical and/or related area of pharmacy practice component.

4. Advanced practice experience may be gained within non-licensed programs, provided these programs have received prior approval by the board. The board shall make its determination concerning program approval and the number of hours to grant to an approved program through review of an application. The board may request additional information, interview program participants or complete site inspections before a decision on an application is made.

(C) Advanced practice experience shall be computed from the date of licensure as a pharmacy intern.

(D) Reports must be filed by the intern with the board in order for any hours to be counted toward the required practical experience. The reports shall include, but not be limited to:

1. Application for licensure as an intern; and

2. Academic internship report(s).

(E) Advanced practice experience in intern training giv-



en in a state other than Missouri may be allowed by the board if, in the opinion of the board, the requirements of the state of the applicant's residence and experience are equal in the minimum requirements of the board for intern training in Missouri. Intern hours earned in another state must be certified directly to the State Board of Pharmacy from the board of pharmacy of the state in which the training occurred.

(F) A pharmacy preceptor shall be a licensed pharmacist in good standing with the board.

(G) Emphasis must be on activities connected with pharmaceutical care through the interpretation and evaluation of prescription orders; the compounding, dispensing and labeling of drugs and devices pursuant to prescription orders; the proper and safe storage of drugs and devices and the maintenance of proper records of them; and consultation with patients and other health care practitioners about the safe and effective use of drugs and devices.

(H) The provisions of this rule are not applicable to those students who gain their advanced practice experience in another state. The minimum practical experience shall be fifteen hundred (1,500) hours of advanced practice experience to qualify to take the examination for licensure as a pharmacist. If any portion of the required fifteen hundred (1,500) hours are to be earned in Missouri, the applicant must be licensed as an intern under the provisions of this rule. When intern hours are to be earned within the state of Missouri by a student enrolled in or by a graduate of an out-of-state accredited school of pharmacy, the candidate must apply directly to the board of pharmacy to seek approval of any site and preceptor to be used. Any pharmacy that is submitted for approval as an intern training site for an out-of-state student or graduate shall meet the criteria outlined in (4)(A)1.-3.

#### (4) Requirements for a Advanced Practice Experience Training Pharmacy.

(A) Requirements for a licensed pharmacy to participate as a site for practical experience training that is approved by the board include the following:

1. It must be a pharmacy with a clear record with respect to the observance of all federal, state and municipal laws and ordinances governing any phase of activity in which the pharmacy is engaged;

2. It must be a pharmacy operating under a pharmacy permit issued by the board and it must remain in good standing with the board; and

3. All interns will be under the direct supervision of a licensed pharmacist in good standing.

(B) Institutional settings that are involved in training interns must maintain a pharmacy permit and comply with all other provisions of this rule. In addition, any inpatient areas of an institution used to train interns will be subject to regular inspection by the board. A school of pharmacy may petition the board for an exception to this require-

ment in order to allow the facility to be approved for providing advanced practice experience training.

(C) Accredited schools of pharmacy located within this state shall provide to the board, on an annual basis, a list of all preceptors and sites that are used in providing advanced practice experience through rotations toward the advanced practice experience requirement. The board shall approve any site for training interns that will be used within the college curriculum to fulfill the advanced practice experience requirements for licensure as a pharmacist. Any preceptors or sites that may be added by a school outside the annual approval process of the board must be approved by the board before the site can be used for practical experience purposes. In addition, the board shall approve the training standards, policies and procedures that are proposed by the schools of pharmacy in fulfilling the advanced practice experience requirements.

(D) Interns that have accumulated hours outside of the school of pharmacy program may submit those hours for credit up to one (1) year from the date that the requirements for advanced practice experience are in effect. All other requirements involving licensure, training and reporting to the board of pharmacy shall be adhered to before any credit of hours is provided.

#### (5) Examination.

(A) Each applicant for licensure by examination must pass the National Association Boards of Pharmacy Licensure Examination (NAPLEX) and the Multistate Pharmacy Jurisprudence Examination (MPJE). The applicant is responsible for payment of any required fee for the NAPLEX and the MPJE examinations, as established by the National Association of Boards of Pharmacy.

(B) A minimum score of seventy-five (75) is required for each of the examinations listed in subsection (5)(A).

(C) All examinations are scored independently and may be retaken independently upon payment of the appropriate fee.

(D) The MPJE will consist of questions on Missouri and federal pharmacy laws and regulations and the Missouri and federal controlled substance laws and regulations.

(E) If a candidate fails to achieve a score of seventy-five (75) in any of the examinations listed in subsection (5)(A), it will be necessary to take that examination again and pass that examination before a license can be issued. The candidate must complete any required application(s) and pay any required fee(s) to reestablish eligibility to retake any of the examinations listed in subsection (5)(A).

(F) A candidate scheduled to write the NAPLEX may apply for licensure by completing the NAPLEX Score Transfer Form supplied by the National Association of Boards of Pharmacy. In addition to completion of the form, the candidate must fulfill all necessary requirements as set forth by the National Association of Boards

of Pharmacy and the State Board of Pharmacy. Any fees required to transfer scores must accompany the completed form. Transfer scores will be accepted by the board from any state which accords similar privileges to Missouri candidates. Scores transferred by the candidate to Missouri must meet all minimum grade requirements as set forth in section (5) of this rule. Once this has been determined, the board office will send an application form for Missouri licensure to the successful candidate. The candidate must return the completed form along with all appropriate fees to the board office. The candidate must successfully complete the Multistate Pharmacy Jurisprudence Examination (MPJE) at the next regular examination date. Any candidate who fails to achieve a passing score on any of the examinations required may retake the examination upon proper reapplication and upon payment of appropriate fees.

(G) When the applicant's examination application has been accepted, the board will notify the National Association of Boards of Pharmacy that the applicant is an eligible candidate for the NAPLEX automated examination and/or the MPJE automated examination. The applicant is responsible for completing any necessary application(s) and payment of fee(s) as required by the National Association of Boards of Pharmacy.

(H) The National Association of Boards of Pharmacy will then create an applicant data-base of eligible candidates for the NAPLEX and/or the MPJE which will be provided to the entity or entities which manages the testing centers. The National Association of Boards of Pharmacy will cause an Authorization to Test and instructions for scheduling a test appointment for either or both computerized examinations (NAPLEX and MPJE) to be mailed directly to the candidate. It will be the candidate's responsibility to schedule his/her testing date, time and location for either or both computerized examinations (NAPLEX and MPJE).

(I) The score on the NAPLEX examination will be reported to the National Association of Boards of Pharmacy by the testing center(s) and subsequently to the board of pharmacy.

#### (6) Licensure Transfer.

(A) An applicant for licensure transfer must fully meet all the requirements in effect in Missouri on the date of registration in the state of original licensure.

(B) An applicant for licensure transfer shall meet all requirements of the state from which they are transferring including, but not limited to, that state's continuing education requirements.

(C) An applicant for licensure transfer must have attained the equivalent of fifteen hundred (1,500) practice hours, as set forth in section (3) of this rule, either as a pharmacy intern/extern or have maintained a pharmacist license in good standing for a period of not less than one (1) year in the state from which they are transferring.

(D) The board, in its discretion, may grant licensure

transfer to an applicant when the applicant previously has taken and failed to pass an examination given by the Missouri

board and who is eligible for licensure transfer, having later passed the examination for registry in another state.

(E) Applicants for licensure transfer must pass the Multistate Pharmacy Jurisprudence Examination (MPJE), a computerized examination provided through the National Association of Boards of Pharmacy. The applicant for licensure transfer is responsible for completing any necessary application(s) and payment of fee(s) as required by the National Association of Boards of Pharmacy. If the applicant fails the MPJE two (2) consecutive times, the application will be provided to the full board at its next regular meeting for appropriate review and action.

(F) No person shall be eligible for licensure transfer against whom there is pending any indictment or any alleged violation of the laws governing the practice of pharmacy, alcohol or other regulated law or who has been convicted of any crime within the past ten (10) years.

(G) All required fees must be paid prior to approval of a licensure transfer.

(H) The State Board of Pharmacy reserves the right to reject any licensure transfer application for good and just reasons and, in the event of so doing, the fee paid to it will be refunded.

(I) No application for licensure transfer will remain valid if the applicant fails to complete the transfer process as outlined in this rule within six (6) months of receipt of the application by the board. Any failure by the applicant to complete the licensure transfer process will result in a forfeiture of all fees paid to the board.

(J) Any application for licensure transfer which is pending for three (3) months or more and is still a valid application may require an additional review by the board of licensure information from any state in which the applicant holds a license. Any applicant who provides a complete and truthful application to the board, completes the licensure process in less than three (3) months and is successful in passing the Multistate Jurisprudence Examination on the first attempt, will not be required to register as a technician while working in a licensed pharmacy or acting in any capacity that would require licensure as a pharmacist as defined in section 338.010.1, RSMo. Direct supervision of an applicant by a licensed pharmacist is required at all times when any functions related to section 338.010, RSMo are performed. Any licensure transfer applicant who must subsequently apply for registration as a technician will not be required to provide fingerprints if

all fingerprinting requirements have previously been fulfilled within the licensure transfer process.

#### (7) Licenses.

(A) No duplicate certificates or renewals for licenses

or permits shall be issued except upon the return of the original or upon the statement that the certificate has been lost or destroyed. The duplicate certificate or renewal fee shall accompany the affidavit.

**AUTHORITY:** sections 338.020, 338.040, 338.070, 338.140, and 338.280, RSMo 2000 and sections 338.030 and 338.035, RSMo Supp. 2007.\* This rule originally filed as 4 CSR 220-2.030. This version of rule filed July 18, 1962, effective July 28, 1962. Amended: Filed Nov. 9, 1966, effective Nov. 19, 1966. Amended: Filed Nov. 27, 1967, effective Dec. 7, 1967. Amended: Filed Sept. 30, 1969, effective Oct. 10, 1969. Amended: Filed Dec. 31, 1975, effective Jan. 10, 1976. Emergency amendment filed July 15, 1981, effective Sept. 28, 1981, expired Nov. 11, 1981. Amended: Filed Aug. 10, 1981, effective Nov. 12, 1981. Amended: Filed April 14, 1982, effective July 11, 1982. Amended: Filed Dec. 12, 1983, effective May 11, 1984. Amended: Filed Dec. 11, 1984, effective March 11, 1985. Amended: Filed June 14, 1985, effective Aug. 26, 1985. Amended: Filed Feb. 25, 1986, effective June 12, 1986. Amended: Filed Oct. 1, 1987, effective Jan. 29, 1988. Amended: Filed Jan. 3, 1990, effective April 26, 1990. Amended: Filed Jan. 30, 1991, effective July 8, 1991. Amended: Filed Jan. 3, 1992, effective June 25, 1992. Amended: Filed Aug. 4, 1992, effective April 8, 1993. Amended: Filed Sept. 26, 1994, effective March 30, 1995. Amended: Filed Jan. 27, 1995, effective Sept. 30, 1995. Amended: Filed March 19, 1996, effective Oct. 30, 1996. Amended: Filed Dec. 9, 1996, effective July 30, 1997. Amended: Filed April 23, 1998, effective Nov. 30, 1998. Amended: Filed Nov. 1, 2000, effective June 30, 2001. Amended: Filed June 28, 2002, effective Jan. 30, 2003. Amended: Filed Nov. 13, 2002, effective June 30, 2003. Amended: Filed Dec. 1, 2004, effective June 30, 2005. Moved to 20 CSR 2220-2.030, effective Aug. 28, 2006. Amended: Filed Feb. 6, 2008, effective Aug. 30, 2008.

\*Original authority: 338.020, RSMo 1939, amended 1947, 1949, 1981, 1990; 338.030, RSMo 1939, amended 1949, 1951, 1981, 1990, 2001; 338.035, RSMo 1990, amended 1993, 1995, 2007; 338.040, RSMo 1939, amended 1961, 1969, 1981, 1990; 338.070, RSMo 1939, amended 1947, 1953, 1961, 1969, 1981, 1985, 1997; 338.140, RSMo 1939, amended 1981, 1989, 1997; and 338.280, RSMo 1951, amended 1971, 1981.

## **20 CSR 2220-2.032 Licensure by Examination for Graduates of Nonapproved Foreign Pharmacy Schools**

**PURPOSE:** This rule defines requirements for licensure by examination of applicants who are graduates of foreign colleges/schools of pharmacy not approved by the board as outlined in 4 CSR 220-2.030(1).

(1) An individual who is a graduate of a foreign college/school of pharmacy which is not currently accredited by the board may apply to write the examination for licensure, if current requirements for licensure in Missouri are met.

(2) The board shall consider an application only after the applicant submits all of the following required credentials:

(A) Photostatic copy of a certificate, stating name, date of birth and place of birth, by one (1) of the following methods:

1. Birth certificate;
2. Baptismal certificate; or
3. Notarized statement from an authorized agency;

(B) Documentation as required by the board showing proof of practical experience which is equal to the requirements of 4 CSR 220-2.030(2), (3) and (6)(C);

(C) Documentation of name change, if name on the credentials supplied for evaluation purposes is different than the present name appearing on the application;

(D) Copy of current visa, along with a copy of an employment authorization document such as an Alien Registration Receipt Card, Form I-551 or Employment Authorization Card Form I-688-B, or any other document approved or issued by the United States government permitting employment, if applicant is not a United States citizen, or proof of United States citizenship;

(E) One (1), two-inch by two-inch (2"× 2") frontal view portrait photograph of the applicant; and

(F) Foreign Pharmacy Graduate Equivalency Certification (FPGEC) as provided by the National Association of Boards of Pharmacy Foundation Foreign Pharmacy Graduate Examination Committee.

(3) An applicant who successfully completes all requirements as set forth in this rule will be considered eligible to apply and take the licensure examination as outlined in sections 338.020 and 338.030, RSMo and 4 CSR 220-2.030.

(4) An applicant who does not meet the current minimum requirements as set forth by the board for licensure shall be advised of the decision of the board. This decision may include recommendations as to what action the applicant can take to obtain licensure.

(5) Application pursuant to this rule should be submitted to the board's office six (6) months prior to the date for which the candidate wishes to sit for a regularly scheduled licensing examination.

(6) Documents in a foreign language shall be translated into English, notarized by an authorized individual and attached when submitted to the Missouri Board of Pharmacy.

(7) All fees are nonrefundable.

**AUTHORITY:** sections 338.020, 338.030 and 338.140, RSMo 2000.\* This rule originally filed as 4 CSR 220-2.032. Original rule filed Oct. 16, 1985, effective Feb. 24, 1986. Amended: Filed Dec. 24, 1990, effective June 10, 1991. Amended: Filed Dec 15, 1995, effective July 30, 1996. Amended: Filed Nov. 21, 1997, effective June 30, 1998. Amended: Filed March 1, 2001, effective Sept. 30, 2001. Moved to 20 CSR 2220-2.032, effective Aug. 28, 2006.

\*Original authority: 338.020, RSMo 1939, amended 1947, 1949, 1981, 1990; 338.030, RSMo 1939, amended 1949, 1951, 1981, 1990; 338.140, RSMo 1939, amended 1981, 1989, 1997.

## **20 CSR 2220-2.034 Licensure by Reciprocity for Graduates of Nonapproved Foreign Pharmacy Schools Who Have Been Licensed in Another State**

**PURPOSE:** This rule defines requirements for licensure by reciprocity of applicants who are graduates of foreign colleges/schools of pharmacy not approved by the board as outlined in 4 CSR 220-2.030(1) who have been licensed in another state.

(1) An individual who is a graduate of a foreign college/school of pharmacy not approved by the Missouri Board of Pharmacy and is licensed as a pharmacist by another state may apply for licensure in this state by reciprocity, if the requirements for licensure by the other state are equivalent to those of this state.

(2) The applicant for reciprocal licensure must fulfill all requirements as set forth in 4 CSR 220-2.032.

(3) Appropriate fees must accompany all applications and are nonrefundable.

(4) Once the credentials of a candidate have been approved by the board, application to the National Association of Boards of Pharmacy for reciprocity to Missouri may begin. All reciprocal licensure requirements as set forth in 4 CSR 220-2.030(6) must then be satisfactorily completed.

**AUTHORITY:** sections 338.020 and 338.030, RSMo Supp. 1990.\* This rule originally filed as 4 CSR 220-2.034. Original rule filed Oct. 16, 1985, effective Feb. 24, 1986. Amended: Filed Aug. 29, 1986, effective Dec. 25, 1986. Amended: Filed Dec. 24, 1990, effective June 10, 1991. Moved to 20 CSR 2220-2.034, effective Aug. 28, 2006.

\*Original authority: 338.020, RSMo 1939, amended 1947, 1949, 1981, 1990 and 338.030, RSMo 1939,

amended 1949, 1951, 1981, 1990.

## **20 CSR 2220-2.036 Temporary License**

**PURPOSE:** This rule defines requirements to obtain a temporary license to practice pharmacy for persons completing residency programs.

(1) Temporary licenses issued under authority granted to the board in section 338.043, RSMo for purposes of completing a residency training or fellowship program shall limit the right of the licensee to practice only in locations approved by the board under the supervision of a pharmacist licensed to practice pharmacy in this state.

(A) The pharmacist license of the supervising pharmacist must be an active, unrestricted license and be in good standing with the board.

(B) All locations where the temporary licensee shall practice must be provided to the board when initially applying for a temporary license and must be updated when changes occur during the licensing period.

(2) An applicant for a temporary license for use in completing a postgraduate training program in pharmacy as recognized by the board is required to make application upon a form supplied by the board.

(A) No application will be considered unless it is fully completed and properly attested.

(B) A frontal view portrait photograph which measures two inches by two inches (2" x 2") must accompany the application for a temporary license.

(C) The application shall be submitted along with the appropriate licensure fee as required by the board.

(D) The application must be accompanied by a protocol which will outline the duties of the temporary licensee as well as any documentation concerning affiliations with licensed pharmacies, other institutions or associations, or all. The protocol shall define and provide, at a minimum, the following:

1. Type of practice to be performed and a specific job description of professional duties and functions to be completed;

2. Identity of the supervising pharmacist which includes a statement attesting to the ability and understanding of responsibilities involved;

3. A complete listing of all affiliations to be utilized during the licensure period; and

4. A complete listing of all locations where professional services shall occur.

(3) In the event that an applicant for temporary licensure is not a graduate of a board approved school or college of pharmacy as outlined in 20 CSR 2220-2.030(1), then all the requirements as outlined in 20 CSR 2220-2.032 must be completed.

(4) A Missouri licensed pharmacist who agrees to super-

vises a temporary licensee shall conduct general supervision during his/her tenure.

(A) General supervision is defined as supervision required to fulfill the stated requirements of the practice protocol or may be required by the board and to insure appropriate outcomes as to training received or provided. In addition, general supervision requires that the supervisor be available for consultation with the licensee whenever necessary. Any proposed methods for supervising temporary licensees shall be stated in the practice protocol.

(B) General supervision also will include the timely submission of reports to the board as may be required through protocol or by the board in assessing outcomes or adherence to board requirements.

(5) The board may terminate a temporary license at its own discretion if, in the opinion of the board, any of the requirements of the board or the approved protocol have not been adhered to. The licensee shall be notified in writing by personal service or certified mail when board action results in the termination of a temporary license.

(6) No applicant for a temporary license shall commence practicing until the temporary license is issued.

(7) The temporary licensing program is not intended to replace or conflict with any requirements or provisions of 20 CSR 2220-2.030 as regards internship or externship. Students who rotate through a licensed pharmacy or other accredited internship site shall apply for a temporary license when the student is not currently licensed as an intern or registered as a technician. For purposes of this section to qualify for a temporary license the rotation shall be no more than six (6) weeks in length and the student cannot have been previously licensed as an intern by the board.

(8) If a temporary licensee desires to acquire a permanent license or desires to practice pharmacy outside of the provisions of this rule, then all provisions as outlined in 20 CSR 2220-2.030 must be completed.

(9) A temporary license automatically expires at the end of the applicant's Missouri-based training program identified in the application and protocol. No temporary licensee shall continue to practice pharmacy beyond the expiration date of the license.

(10) Temporary licenses may be issued to licensure transfer candidates or licensure examination candidates who successfully complete the requirements for permanent licensure if background criminal checks are not complete.

(11) Any temporary license issued in lieu of a permanent license while a criminal background check is completed shall remain in effect until the permanent license is is-

sued or denied. A copy of proof of licensure from the Division of Professional Registration, Board of Pharmacy website may be used as proof of licensure by an applicant until delivery of a hard copy license is completed to the applicant.

(12) If a permanent license is denied, the board shall inform the applicant in writing of the denial. The temporary license will be considered invalid after notification is sent to the applicant by certified mail.

(13) All fees are nonrefundable.

*AUTHORITY: section 338.140, RSMo 2000 and section 338.043, RSMo Supp. 2007.\* This rule originally filed as 4 CSR 220-2.036. Original rule filed May 24, 1993, effective Dec. 9, 1993. Amended: Filed Nov. 21, 1997, effective June 30, 1998. Amended: Filed March 15, 2000, effective Sept. 30, 2000. Moved to 20 CSR 2220-2.036, effective Aug. 28, 2006. Amended: Filed Feb. 6, 2008, effective Aug. 30, 2008.*

*\*Original authority: 338.043, RSMo 1990, amended 1997, 2001 and 338.140, RSMo 1939, amended 1981, 1989, 1997.*

## **20 CSR 2220-2.050 Public Complaint Handling and Disposition Procedure**

*PURPOSE: This rule establishes a procedure for the receipt, handling and disposition of public complaints by the board, pursuant to the mandate of section 620.010.16(6), RSMo.*

(1) The State Board of Pharmacy shall receive and process each complaint made against any licensee or registrant or other person or entity, which complaint alleges certain acts or practices which may constitute one (1) or more violations of the provisions of Chapter 338, RSMo. Any member of the public, the profession or any federal, state or local official may make and file a complaint with the board. Complaints shall be received from sources outside Missouri and will be processed in the same manner as those originating within Missouri. No member of the State Board of Pharmacy shall file a complaint with this board while s/he holds that office, unless that member excuses him/herself from further board deliberations or activity concerning the matters alleged within that complaint. Any staff member or employee of the board may file a complaint pursuant to this rule in the same manner as any member of the public.

(2) Complaints should be mailed or delivered to the following address: State Board of Pharmacy, 3605 Missouri Blvd., PO Box 625, Jefferson City, MO 65102. However, actual receipt of the complaint by the board at its administrative offices in any manner shall be sufficient. Com-

plaints may be based upon personal knowledge or upon information and belief, reciting information received from other sources.

(3) All complaints shall be made in writing and shall fully identify their maker by name and address. Complaints may be made on forms provided by the board, which shall be available upon request. Complaints need not be made by affidavit, but oral or telephone communications will not be considered or processed as complaints. Any person attempting to make an oral or telephone complaint against an individual will be provided with a complaint form and requested to complete it and return it to the board. Any staff member or employee of the board may make and file a complaint based upon information and belief, in reliance upon oral, telephone or written but unsigned communications received by the board, unless those communications are believed by that staff member or employee to be false.

(4) Each complaint received under this rule shall be recorded by the board. Complaints shall be logged in consecutive order as received. The record shall contain each complainant's name and address; the name and address of the subject(s) of the complaint; the date each complaint is received by the board; a brief statement of the acts complained of, and the ultimate disposition of the complaint. This record shall be a closed record of the board.

(5) The complainant shall be informed in writing as to whether the complaint has been dismissed by the board or is being referred to legal counsel for legal action. The complainant may be notified of the ultimate disposition of the complaint, excluding judicial appeals and may be provided with a copy of the decisions (if any) of the Administrative Hearing Commission and the board. The provisions of this section shall not apply to complaints filed by staff members or employees of the board, based upon information and belief, acting in reliance on third-party information received by the board.

(6) Both the complaint and any information obtained as a result of the complaint investigation shall be considered a closed record of the board and shall not be available for inspection by the public.

(7) This rule shall not be deemed to limit the board's authority to file a complaint with the Administrative Hearing Commission or with a court, charging a licensee, permittee or other person or entity with any actionable conduct or violation, whether or not this complaint exceeds the scope of the acts charged in a preliminary public complaint filed with the board and whether or not any public complaint has been filed with the board.

(8) The board interprets this rule, which is required by

law, to exist for the benefit of those members of the public who submit complaints to the board. This rule is not deemed to protect, or to inure to the benefit of those licensees, permit holders, registrants or other persons or entities against whom the board has instituted or may institute administrative or judicial proceedings concerning possible violations of provisions of Chapter 338, RSMo.

(9) To facilitate the investigation, evaluation and disposition of complaints, which involve violations of federal and state law governing controlled substances, the Board of Pharmacy may designate Bureau of Narcotics and Dangerous Drugs personnel and other state personnel as pharmacy inspectors. These inspectors shall be authorized pursuant to section 338.150, RSMo to enter and inspect various premises.

(10) Persons designated by the Board of Pharmacy as pharmacy inspectors and other Board of Pharmacy personnel may attend board meetings in order to assist the board in its deliberations.

*AUTHORITY: sections 338.140 and 338.280, RSMo 2000 and 620.010.15(6), RSMo Supp. 2004.\* This rule originally filed as 4 CSR 220-2.050. Original rule filed Jan. 11, 1982, effective June 1, 1982. Amended: Filed Aug. 27, 1985, effective Nov. 11, 1985. Amended: Filed Aug. 29, 1986, effective Dec. 25, 1986. Amended: Filed Sept. 26, 1994, effective March 30, 1995. Amended: Filed June 28, 2002, effective Jan. 30, 2003. Amended: Filed May 13, 2005, effective Oct. 30, 2005. Moved to 20 CSR 2220-2.050, effective Aug. 28, 2006.*

*\*Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997; 338.280, RSMo 1951, amended 1971, 1981; and 620.010.15(6), RSMo 1973, amended 1981, 1983, 1986, 1989, 1990. 1993, 1994, 1995, 1999, 2001.*

## **20 CSR 2220-2.060 Gold Certificates**

*PURPOSE: This rule sets requirements concerning the issuance of honorary gold certificates to pharmacists licensed in Missouri for fifty years.*

(1) The Missouri Board of Pharmacy shall issue gold certificates to all pharmacist licensees who have been regularly licensed as pharmacists in Missouri for fifty (50) years. These gold certificates shall be distinctive in coloration and text from other documentary licenses issued by the board and shall be designed to appropriately recognize each recipient pharmacist for his/her half century of professional practice. Gold certificates are honorific in nature and confer no right to practice pharmacy upon the recipient.

(2) The awarding of gold certificates shall be made by

the Missouri Board of Pharmacy routinely and without charge to the recipient.

*AUTHORITY: section 338.140, RSMo Supp. 1989.\* This rule originally filed as 4 CSR 220-2.060. Original rule filed March 14, 1983, effective June 11, 1983. Moved to 20 CSR 2220-2.060, effective Aug. 28, 2006.*

*\*Original authority: 338.140, RSMo 1939, amended 1981, 1989.*

## **20 CSR 2220-2.080 Electronic Data Processing**

*PURPOSE: This rule establishes requirements for utilizing an electronic data processing system in a pharmacy.*

(1) All information concerning the compounding, dispensing or selling at retail of any drug, medicine or poison pursuant to a lawful prescription which is entered into an electronic data processing (EDP) system at any pharmacy shall be entered only by a licensed pharmacist or by an individual under the direct supervision and review of a licensed pharmacist. That pharmacist shall be personally responsible for the accuracy of the information.

(2) Any EDP system used by any pharmacy for record keeping shall comply with the requirements of section 338.100, RSMo, including the capability to store and retrieve the following information concerning the filling or refilling of any prescription:

(A) A prescription label number that is linked to the unique readily retrievable identifier;

(B) Date of original prescription, expiration date of the prescription or both;

(C) Date original prescription was filled;

(D) Patient's full name;

(E) Patient's address when a prescription prescribes a controlled substance;

(F) Prescriber's full name;

(G) Prescriber's address and Drug Enforcement Administration (DEA) number when a prescription specifies a controlled substance;

(H) Name of drug, medicine or poison dispensed;

(I) Quantity of drug, medicine or poison originally dispensed;

(J) Quantity of drug, medicine or poison dispensed on each refill;

(K) Initials or code of the pharmacist responsible for input or review of data on each original prescription and each refill;

(L) Date of each refill; and

(M) If a new prescription is transmitted by phone, a hard copy representation must be made and contain all of the information in subsections (2)(A)–(L) plus an indication of whether or not a generic substitution is permitted and made in accordance with 4 CSR 220-3.011.

(3) Prescription hard copies must be filed by either the prescription label number or by the unique readily retrievable identifier. Pre-prescription hard copies must be retrievable at the time of inspection.

(4) Any pharmacy using an EDP system as described in section (1) shall provide documentation that the information concerning the refills of prescriptions entered into the system for all prescription drugs is accurate. This documentation shall include:

(A) The initials or code designation of the dispensing pharmacist for each refill;

(B) The date of the refill;

(C) The quantity of substances refilled;

(D) The number of authorized refills or dispensable units remaining;

(E) If additional refills are authorized and added to an existing prescription, a notation indicating the method and source of the authorization must be a part of the EDP record or hard copy, in that case the expiration date of the original prescription shall remain the same; and

(F) If any other alteration is made in the original prescription record, a clear audit trail must be maintained. This shall include, but is not limited to, a change in authorizing physician, a change in total quantity ordered or a change in directions.

(5) Any pharmacy using an EDP system as described in section (1) shall maintain the following:

(A) A bound logbook or separate file in which each pharmacist involved in the pharmacy's record keeping system shall sign a statement each day attesting that information concerning the refill of prescriptions has been entered into the system for that day and that the pharmacist has reviewed the information for accuracy. The logbook or file shall be maintained at the pharmacy for at least five (5) years after the date the drugs, medicines or poisons are dispensed.

(6) Any hospital pharmacy using an EDP system, as described in section (1), for outpatient prescriptions, employee prescriptions and take-home prescriptions shall conform to all sections of this rule.

(7) Any EDP system, as described in section (1), must be capable of producing the record required in subsections (2)(A)–(M) and said records shall be readily retrievable on-line. Readily retrievable is defined as providing EDP records within two (2) hours of time of request by an inspector or by making a computer terminal available to the inspector for immediate use.

(8) An auxiliary record keeping system shall be established for the documentation of refills if the EDP system is inoperative for any reason. The auxiliary system shall insure that all refills are authorized by the original prescription or prescriber. When this EDP system is re-

stored to operation, the information regarding prescriptions filled and refilled during the inoperative period shall be entered into the EDP system within seven (7) working days. However, nothing in this section shall preclude the pharmacist from using his/her professional judgment for the benefit of a patient's health and safety.

(9) If a prescription is transferred from a pharmacy using an EDP system, a notation or deactivation must be made on the transferred record to preclude any further dispensing. If the same prescription is transferred back into the original pharmacy, it shall be treated as a new record, showing the original date written and expiration date.

(10) Prior to or simultaneously with the purging of any EDP system, the pharmacist-in-charge or permit holder shall make certain that a record of all prescription activity being erased exists in readable form, either on paper, microfiche or electronic media storage. A pharmacy that desires to discard hard copy prescriptions that are more than three (3) years old must maintain all prescription information on microfiche or electronic media. Any process utilizing microfiche must ensure that all data is available and in readable form. Any pharmacy opting for the utilization of microfiche records must also maintain a microfiche reader so that records may be reviewed on-site by pharmacy personnel or board inspectors. Electronic media storage is defined as any medium such as a computer, floppy disk or diskette, compact disk (CD) or other electronic device that can reproduce all prescription information as required by section 338.100, RSMo and this rule and is retrievable within three (3) working days.

(11) If coded information exists in the electronic EDP, the board inspector may request the definitions of the codes from the pharmacist on duty for immediate review.

(12) The EDP system shall be able to provide a listing of drug utilization for any drug for a minimum of the preceding twelve (12)-month period. Drug utilization information shall be available by specific drug product, patient name or practitioner. If requested to do so, the pharmacy shall have three (3) working days to provide the report.

(13) The provisions of this rule shall not conflict with any federal laws or regulations. If any part of this rule is declared invalid by a court of law, that declaration shall not affect the other parts of the rule.

**AUTHORITY:** sections 338.100, 338.140 and 338.280, RSMo 2000.\* This rule originally filed as 4 CSR 220-2.080. Original rule filed March 8, 1984, effective Aug. 11, 1984. Amended: Filed Nov. 4, 1985, effective Feb. 24, 1986. Rescinded and readopted: Filed Dec. 5, 1988, effective March 11, 1989. Amended: Filed March 15,

2000, effective Sept. 30, 2000. Amended: Filed Nov. 1, 2000, effective June 30, 2001. Moved to 20 CSR 2220-2.080, effective Aug. 28, 2006.

\*Original authority: 338.100, RSMo 1939, amended 1971, 1990, 1997, 1999; 338.140, RSMo 1939, amended 1981, 1989, 1997; and 338.280, RSMo 1951, amended 1971, 1981.

## **20 CSR 2220-2.085 Electronic Transmission of Prescription Data**

**PURPOSE:** This rule establishes basic guidelines to address new technology for the transmission of prescription data utilizing electronic mediums.

### **(1) Definitions.**

(A) Electronic transmission prescription—Includes transmission of both image and data prescriptions.

(B) Electronic image transmission prescription—Any prescription order for which an exact visual image of the order is received by a pharmacy from a licensed prescriber.

(C) Electronic data transmission prescription—Any prescription order, other than an electronic image transmission prescription, which is electronically transmitted from a licensed prescriber to a pharmacy.

(D) Electronic signature—Means a confidential personalized digital key, code, number or other identifier used for secure electronic data transmissions which identifies and authenticates the signatory. Electronic signatures may be sent as part of an electronic transmission prescription to a pharmacy or it may be applied to a hard copy to be provided to the patient.

(2) When a prescription is transmitted to a pharmacy electronically, the following requirements must be met:

(A) The original electronic facsimile transmission (FAX) document or all information from an electronic source must be readily retrievable through the pharmacy computer system;

(B) To maintain the confidentiality of patient records, the system shall have adequate security and systems safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records. Once the drug has been dispensed, any alterations in prescription drug order data shall be documented including the identification of the pharmacist responsible for the alteration;

(C) In verifying the authenticity of a transmitted prescription, the pharmacist shall ensure the validity of the prescription as to its source of origin. Measures to be considered in authenticating prescription drug orders received via electronic transmission include:

1. Maintenance of a practitioner's facsimile number reference or other electronic signature file;
2. Verification of the telephone number of the originat-



ing facsimile equipment;

3. Telephone verification with the practitioner's office that the prescription as both written by the practitioner and transmitted by the practitioner or the practitioner's authorized agent;

4. Other efforts which, in the professional judgment of the pharmacist, may be necessary to ensure the transmission was initiated by the prescriber;

(D) At the option of the patient, an electronically produced prescription may be sent to a pharmacy electronically or provided as a hard copy generated from the prescriber's electronic prescribing system;

(E) Hard copy prescriptions presented to the patient generated from electronic media shall be applied to paper that utilizes security features that will ensure that the prescription is not subject to any form of copying and/or alteration; and

(F) Electronic transmission technology utilized by pharmacy personnel shall not be used to circumvent or violate any provision of state and federal drug laws or the Pharmacy Practice Act and accompanying regulations.

*AUTHORITY: sections 338.010, 338.095 338.140 and 338.280, RSMo 2000.\* This rule originally filed as 4 CSR 220-2.085. Original rule filed Sept. 25, 1995, effective April 30, 1996. Amended: Filed July 28, 2000, effective Jan. 30, 2001. Amended: Filed April 16, 2001, effective Nov. 30, 2001. Moved to 20 CSR 2220-2.085, effective Aug. 28, 2006.*

*\*Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990; 338.095, RSMo 1993; 338.140, RSMo 1939, amended 1981, 1989, 1997; and 328.280, RSMo 1951, amended 1971, 1981.*

## **20 CSR 2220-2.090 Pharmacist-in-Charge**

*PURPOSE: This rule defines the term pharmacist-in-charge, sets the requirements and standards for this title, and defines the term full-time pharmacy.*

(1) A pharmacist may be a pharmacist-in-charge of a licensed pharmacy; provided, that s/he complies with all provisions of this rule.

(2) The responsibilities of a pharmacist-in-charge, at a minimum, will include:

(A) The management of the pharmacy must be under the supervision of a Missouri-licensed pharmacist at all times when prescriptions are being compounded, dispensed or sold;

(B) The traffic in the prescription area must be restricted to authorized personnel only so that proper control over the drugs can be maintained at all times;

(C) All the required signs are displayed in the appropriate places when there is no pharmacist on duty;

(D) The licenses of all pharmacists employed are con-

spicuously displayed in the pharmacy;

(E) Assurance that all procedures of the pharmacy in the handling, dispensing and recordkeeping of controlled substances are in compliance with state and federal laws;

(F) Any excessive or suspicious requests, or both, for the dispensing of controlled substances be verified prior to dispensing;

(G) All labeling requirements are complied with according to section 338.059, RSMo, federal laws where required and board regulations governing auxiliary labeling of drugs and devices;

(H) The prescription files are maintained according to the requirements of this board and the other state and federal controlled substance laws and regulations;

(I) The Missouri Revised Negative Drug Formulary and state laws governing drug substitution be complied with when generic substitution takes place;

(J) If exempt narcotics are sold, complete records be kept of all exempt narcotics in a bound exempt narcotic register;

(K) If poisons are sold, the pharmacy maintain a poison register;

(L) The pharmacy maintain and have on file at all times the required reference library;

(M) The pharmacy be kept in a clean and sanitary condition;

(N) The pharmacist-in-charge will be responsible for the supervision of all pharmacy personnel, to assure full compliance with the pharmacy laws of Missouri;

(O) All Missouri and federal licenses are kept up-to-date;

(P) Policies and procedures are in force to insure safety for the public concerning any action by pharmacy staff members or within the pharmacy physical plant;

(Q) All equipment, as prescribed through regulation, is available and in good working order;

(R) Security is sufficient to insure the safety and integrity of all legend drugs located in the pharmacy;

(S) Any changes of the following are appropriately carried out:

1. Pharmacy permit transfer of any type or manner;

2. Regulation requirements completed satisfactorily when a change of pharmacist-in-charge occurs;

3. Change of pharmacist's own address as it appears on his/her license;

(T) When the board-recognized pharmacist-in-charge is changed at that licensed facility, an appropriate documented inventory of controlled substances must be taken;

(U) Assure that the appropriate handling and disposal of controlled substances is done and verified through appropriate documentation and when necessary that controlled substances be disposed of through appropriate procedures involving the Missouri Board of Pharmacy or the Bureau of Narcotics and Dangerous Drugs;

(V) No outdated drugs are dispensed or maintained

within the active inventory of the pharmacy, including prescription and related nonprescription items;

(W) Assure full compliance with all state and federal drug laws and rules;

(X) Compliance with state and federal requirements concerning drug samples;

(Y) Assure that all state and federal laws concerning drug distribution and control are complied with and that no violations occur that would cause a drug or device or any component thereof to become adulterated or misbranded;

(Z) Maintain compliance with all state and federal laws governing drug distributor activities and assure that appropriate licensure as a drug distributor is secured if lawful thresholds for unlicensed drug distributions are exceeded;

(AA) Assure overall compliance with state and federal patient counseling requirements;

(BB) Maintain a current list of all personnel employed by the pharmacy as pharmacy technicians. The list shall include the name, registration number or a copy of an application for registration that has been submitted to the board and a description of duties to be performed by each person contained on the list;

(CC) Maintain written standards setting out the responsibilities of registered pharmacy technicians as well as the procedures and policies for supervision of registered pharmacy technicians, as required by 4 CSR 220-2.700(1). Said standards shall be available to the board and its designated personnel for inspection and/or approvals;

(DD) Any person other than a pharmacist or permit holder who has independent access to legend drug stock on a routine basis in a pharmacy shall be required to register with the board as a pharmacy technician. The determination of whether or not an individual must register as a pharmacy technician will be the responsibility of the pharmacist-in-charge; and

(EE) Maintain compliance of automated dispensing and storage systems with applicable board rules and regulations.

**AUTHORITY:** sections 338.140, 338.240 and 338.280, RSMo 2000.\* This rule originally filed as 4 CSR 220-2.090. Emergency rule filed April 12, 1984, effective April 22, 1984, expired Aug. 20, 1984. Original rule filed April 12, 1984, effective Aug. 11, 1984. Amended: Filed Feb. 25, 1986, effective Aug. 11, 1986. Amended: Filed Jan. 27, 1995, effective Sept. 30, 1995. Amended: Filed Aug. 21, 1998, effective Feb. 28, 1999. Amended: Filed Dec. 30, 1998, effective June 30, 1999. Amended: Filed Nov. 1, 2000, effective June 30, 2001. Moved to 20 CSR 2220-2.090, effective Aug. 28, 2006.

\*Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997; 338.240, RSMo 1951; and 338.280, RSMo 1951, amended 1971, 1981.

## **20 CSR 2220-2.100 Continuing Pharmacy Education**

**PURPOSE:** This rule defines continuing education requirements for relicensure of pharmacists in Missouri.

(1) Commencing with the licensing period beginning November 1, 1985 and for each licensing period after that, no active pharmacist license will be renewed by the Missouri Board of Pharmacy unless the applicant has fulfilled the continuing education requirements as set forth in section 338.060, RSMo of the Pharmacy Practice Act.

(2) A continuing education program for pharmacists means postgraduate studies that have prior approval of the Missouri Board of Pharmacy to fulfill the requirements of continuing education for renewal in Missouri. This may include institutes, seminars, lectures, conferences, workshops, extension study, correspondence courses, teaching, professional meetings, self-study courses and any other methods which may be approved by the board, but in any case, the studies must be pharmacy-related.

(A) Programs shall provide for evaluation methods or examinations to assure satisfactory completion by participants.

(B) The person(s) who is to instruct or who is responsible for the delivery or content of the program shall be qualified, as determined by the board, in the subject matter by education, experience or preparation in the preparation and methods of delivery.

(C) Continuing pharmacy education programs shall be approved by one (1) of the following methods:

1. All continuing pharmacy education programs offered by providers approved by the American Council on Pharmaceutical Education will be accepted as meeting the requirements of continuing education for renewal as a pharmacist in Missouri;

2. The Missouri Board of Pharmacy may approve continuing education programs offered by providers who are not approved by the American Council on Pharmaceutical Education. Criteria for approval of those programs shall be based on the criteria promulgated by the American Council on Pharmaceutical Education in its publication "Accreditation Standards and Guidelines" section on Approval of Providers of Pharmaceutical Education, Pages III-1 through III-C. Application to the board for this approval must be made at least thirty (30) days in advance of the program date to guarantee notification of certification status prior to the date of the program. Applications received less than thirty (30) days prior to the date of the program cannot be guaranteed to be certified prior to the date of the program. Application to the board for this approval shall be made on and in accordance with forms established by the board. The forms shall require detailed information relating to administration and organization, budget and resources, teaching staff, educational content and development, methods of

delivery, facilities and evaluation. No applications for approval of continuing education programs will be accepted less than ten (10) business days from the date such program is offered for continuing education purposes. Applications returned due to errors or for purposes of requesting more information shall not be considered to be received by the office until the requested corrections or information are made and received by the board office. The executive director shall review applications for continuing education programs and may approve or deny such requests. Applicants shall be notified on a timely basis once the decision to approve or deny a program has been made. If an application was received by the board office sixty (60) days or more prior to the date it is scheduled to be offered and the program is denied, the applicant may request an appeal to further review the application by the continuing education committee. The request for appeal must be in writing. In no case shall an applicant be able to appeal a denial of an application if such application was initially received by the board office less than sixty (60) days prior to the date it is scheduled to be offered;

3. Any pharmacist whose primary responsibility is not the education of health professionals who leads, instructs or lectures to groups of nurses, physicians, pharmacists or others on pharmacy-related topics in organized continuing education or in-service programs shall be granted continuing education credit for the time expended during actual presentation upon adequate documentation to the Missouri Board of Pharmacy. Application for approval shall be made in accordance with procedures in section (2) of this rule. Credit for the same presentation or program will be allowed only once during a renewal period;

4. Any pharmacist whose responsibility is the education of health professionals shall be granted continuing education credit only for time expended in leading, instructing or lecturing to groups of physicians, pharmacists, nurses or others on board-approved pharmacy-related topics in an organized continuing education or in-service program outside his/her formal responsibilities in a learning institution. Approval will be requested using procedures in section (2) and submitted to the Missouri Board of Pharmacy. Credit for the same presentation or program will be allowed only once during a renewal period;

5. Credit will be given for undergraduate or graduate studies in any regionally accredited pharmacy, medical or dental educational institution of higher learning. Satisfactory proof of course completion, as required by the board, must be submitted with the renewal notice. The following hourly equivalents will be used by the board in assessing credits:

3 hours college credit = 15 contact hours

2 hours college credit = 10 contact hours

1 hour college credit = 5 contact hours

6. One and one-half (1.5) continuing education unit

(CEU) will be the equivalent of fifteen (15) clock hours of participation in programs approved by the Missouri Board of Pharmacy; and

7. Continuing education hours earned in another state will be accepted by the Missouri Board of Pharmacy provided the hours are acquired within the same renewal period and are certified by the other state board of pharmacy.

(D) No information or advertisements shall contain information that a continuing education program has been approved by the board of pharmacy unless the program is accredited by American Council on Pharmaceutical Education (ACPE) or notification has been received that the program has been approved by the board of pharmacy.

(3) Each licensed pharmacist, instead of submitting proof of the completion of the required continuing education courses, may apply for an inactive license at the time s/he makes application for the renewal of his/her license and pay the required renewal fee. An inactive license then shall be issued and may be renewed during the renewal period. While the inactive license is in effect, the pharmacist shall not practice pharmacy.

(4) The renewal fee will be the same for active and inactive licenses.

(5) Before any inactive license can be reactivated to active status, the licensee shall submit proper evidence that s/he has obtained at least fifteen (15) contact hours for each year that his/her license was inactive. It shall be permissible for the licensee to obtain the required contact hours during any time period, while the license is on inactive status, as long as they are obtained prior to activation to active status.

(6) Any licensee who has a lapsed license and seeks to have it renewed pursuant to section 338.060.2, RSMo shall present proper evidence that s/he has obtained the required number of contact hours during the period that his/her license was lapsed.

(7) A pharmacist first licensed by the board within nine (9) months immediately preceding the biennial renewal date shall be exempt from the continuing pharmacy education requirements for that licensure period.

(8) The president of the board annually will select two (2) board members who will serve along with the executive director as the continuing education committee. The committee will review and decide on applications that have been denied approval and an appeal for further review has been submitted. In addition, the committee will report on its activities and continuing education at board meetings and make recommendations to the board concerning continuing education requirements.

(9) The proof of completion of continuing education requirements shall be submitted with the renewal notice and the appropriate fees by submitting an affidavit that clearly attests to the fact that all continuing education requirements for the purpose of renewal of a pharmacist license have been met and that proof of completion of continuing education credits are maintained by the pharmacist in the form of one (1) or more of the following:

(A) Completed certification from the American Council on Pharmaceutical Education;

(B) Completed certification from the Missouri Board of Pharmacy; or

(C) A letter from another state board of pharmacy stating the program, dates of attendance and number of contact hours that have been approved for renewal by that state board.

(10) Continuing education credits must be earned from the time a renewal cycle begins, until the cycle ends as prescribed by the board. For purposes of this section, the renewal cycle begins on September 1 and ends on a biennial cycle on August 31. Each such form of proof of completion of the required continuing education credits shall be retained by the licensee for the preceding two (2) reporting periods prior to renewal.

(11) The renewal application must be completed correctly and in its entirety in order for it to be processed and the license renewed. Any portion of the application that is incomplete or inaccurate shall result in the rejection of the renewal application and require its return to the applicant for corrections.

(12) The Missouri Board of Pharmacy may elect to audit, with the appropriate accrediting body, any licensee to assess the authenticity and validity of contact hours submitted for relicensure. Failure to provide proof of completion of the necessary required continuing education credits when requested to do so by the board, shall be considered a violation. In accordance with section 338.060, RSMo any licensee that has not completed and retained the required evidence of all required continuing education shall pay any delinquent fees as prescribed by the board and may be subject to disciplinary action pursuant to 338.055, RSMo. The board may also initiate auditing of other past renewal periods and/or require proof of completion of future continuing education credits be submitted with any application for a renewal of a license.

**AUTHORITY:** sections 338.060 and 338.140, RSMo 2000.\* This rule originally filed as 4 CSR 220-2.100. Original rule filed Nov. 9, 1984, effective April 11, 1985. Amended: Filed Nov. 21, 1997, effective June 30, 1998. Amended: Filed March 15, 2000, effective Sept. 30, 2000. Amended: Filed June 28, 2002, effective Jan. 30, 2003. Amended: Filed April 1, 2004, effective Sept. 30,

2004. Amended: Filed June 15, 2005, effective Jan. 30, 2006. Moved to 20 CSR 2220-2.100, effective Aug. 28, 2006.

\*Original authority: 338.060, RSMo 1939, amended 1943, 1947, 1949, 1951, 1981, 1984, 1997, 1999 and 338.140, RSMo 1939, amended 1981, 1989, 1997.

## **20 CSR 2220-2.110 PRN Refills**

**PURPOSE:** This rule clarifies the board's requirements for refills as needed so that the practicing pharmacists in Missouri will have adequate guidelines in this area.

(1) A pharmacist shall not fill or refill any prescription which was written more than one (1) year before being presented to the pharmacist, unless the pharmacist consults with the prescriber and confirms—

(A) That the person for whom the drugs or medicines were prescribed is still under the prescriber's care or treatment;

(B) That the prescriber desires for the person to continue receiving the drugs or medicines; or

(C) If the prescriber answers negatively in either case listed in subsection (1)(A) or (B), the pharmacist shall not fill or refill the prescription, even if the prescription authorizes refills as needed (PRN).

(2) If a pharmacist knows or has reason to believe that a person for whom a prescription has been written is not under the prescriber's care or treatment at the time the prescription is presented for filling or refilling, the pharmacist shall consult with their prescriber and ascertain that the prescriber intends for the person to receive the drugs or medicines. The pharmacist shall do this no matter when the prescription originally was written and even if the prescription authorizes refills PRN.

(3) After the pharmacist has confirmed the information required in sections (1) and (2) of this rule, s/he shall record it in his/her records in a uniform fashion so as to make it readily available for verification by the board or its authorized agents.

**AUTHORITY:** section 338.280, RSMo 1994.\* This rule originally filed as 4 CSR 220-2.110. Original rule filed Dec. 11, 1984, effective March 11, 1985. Moved to 20 CSR 2220-2.110, effective Aug. 28, 2006.

\*Original authority: 338.280, RSMo 1951, amended 1971, 1981.

## **20 CSR 2220-2.120 Transfer of Prescription Information for the Purpose of Refill**

**PURPOSE:** This rule defines record keeping required for transfer of prescription information for the purpose

of refill.

(1) Prescription information shall be transferred for the purposes of refill between licensed pharmacies, provided the prescription information to be transferred meets all of the following criteria:

(A) The prescription information indicates authorization by the prescriber for refilling;

(B) The drug on the prescription information is not a Schedule II controlled substance;

(C) The number of lawfully allowable refills has not been exceeded or the maximum allowable time limit has not been exceeded;

(D) If the transfer involves a controlled substance, all information must be transferred directly between two (2) licensed pharmacists; and

(E) The transfer of original prescription information for a controlled substance listed in Schedules III, IV or V for the purpose of refill dispensing is permissible between pharmacies on a one (1)-time basis only. However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

(2) When a prescription on record is transferred, the following record keeping is required:

(A) The prescription record at the transferring pharmacy shall show all of the following:

1. The word void must appear on the face of the invalidated prescription or be immediately voided within the electronic system when the prescription is transferred;

2. The prescription record shall provide the name of the pharmacy to which it was transferred, the date of transfer and the identity of the transferring pharmacist; and

3. If the transfer involves a controlled substance, the address and Drug Enforcement Administration (DEA) registration number of the pharmacy to which it was transferred and the full name of the pharmacist receiving the prescription information must be recorded;

(B) The prescription record at the receiving pharmacy shall show all of the following, in addition to all other lawfully required information of an original prescription:

1. The prescription record is a transferred prescription record from another licensed location;

2. Date of original issuance;

3. Date of original filling, if different from original issuance date;

4. Original number of refills authorized on the original prescription and the number of remaining authorized refills;

5. Date of last refill;

6. Prescription label number;

7. Identity of licensed pharmacy from which the record was transferred;

8. The identity of the transferring pharmacist provided that pharmacies that share the same database and are

under the same ownership may, instead of transferring prescriptions directly between two (2) pharmacists, transfer a prescription electronically by generating a computer-based report at the transferring pharmacy of any prescriptions that have been transferred out. This record shall be readily retrievable to the transferring pharmacy and board representatives and comply with all of the requirements of this rule, except that the requirement to document pharmacist identity shall not be required unless otherwise required by federal law;

9. If the transfer involves a controlled substance, the address and DEA registration number from the transferring pharmacy must be recorded; and

10. Any electronic transfer must maintain patient confidentiality in accordance with 20 CSR 2220-2.300; and

(C) A computerized transfer of prescription information between licensed pharmacies for the purpose of refill shall meet all the requirements stated in sections (1) and (2) of this rule.

(3) A pharmacy shall complete the transfer within one (1) business day of receiving the request.

**AUTHORITY:** sections 338.100, 338.140, and 338.280, RSMo 2000.\* This rule originally filed as 4 CSR 220-2.120. Original rule filed April 16, 1985, effective Aug. 11, 1985. Amended: Filed May 2, 1989, effective Aug. 24, 1989. Amended: Filed April 23, 1998, effective Nov. 30, 1998. Amended: Filed July 28, 2000, effective Jan. 30, 2001. Moved to 20 CSR 2220-2.120, effective Aug. 28, 2006. Amended: Filed Feb. 6, 2008, effective Aug. 30, 2008.

\*Original authority: 338.100, RSMo 1939, amended 1971, 1990, 1997, 1999; 338.140, RSMo 1939, amended 1981, 1989, 1997; and 338.280, RSMo 1951, amended 1971, 1981.

## **20 CSR 2220-2.130 Drug Repackaging**

**PURPOSE:** This rule establishes requirements for drug repackaging.

**PUBLISHER'S NOTE:** The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. Therefore, the material which is so incorporated is on file with the agency who filed this rule, and with the Office of the Secretary of State. Any interested person may view this material at either agency's headquarters or the same will be made available at the Office of the Secretary of State at a cost not to exceed actual cost of copy reproduction. The entire text of the rule is printed here. This note refers only to the incorporated by reference material.

(1) A pharmacist or pharmacy may prepackage drugs for

other than immediate dispensing purposes provided that the following conditions are met:

(A) Only products which will be directly provided to the patient may be prepackaged;

(B) Containers utilized for prepackaging shall meet, as a minimum requirement, that of Class B container standards as referenced by the United States Pharmacopoeia (USP), which has been incorporated herein by reference. Where applicable, light sensitive containers shall be used;

(C) The maximum expiration date allowed for prepacked drugs shall be the manufacturer's expiration date or twelve (12) months, whichever is less; and

(D) Any prepacked drug must have a label affixed to it which contains, at a minimum, the name and strength of the drug, the name of the manufacturer or distributor, an expiration date as defined in subsection (1)(C) and lot number. Pharmacies that store drugs within an automated counting device may, in place of the required label, maintain records for lot numbers and expiration dates that are required on the label as long as it is fully traceable and is readily retrievable during an inspection.

(2) The term prepacked as used in this rule is defined as any drug which has been removed from the original manufacturer's container and is placed in a dispensing container for other than immediate dispensing to a patient.

*AUTHORITY: sections 338.140 and 338.280, RSMo 2000.\* This rule originally filed as 4 CSR 220-2.130. Original rule filed Dec. 10, 1986, effective May 28, 1987. Amended: Filed Nov. 15, 1988, effective March 11, 1989. Emergency amendment filed July 1, 1991, effective July 26, 1991, expired Nov. 22, 1991. Amended: Filed July 1, 1991, effective Jan. 13, 1992. Amended: Filed July 28, 2000, effective Jan. 30, 2001. Amended: Filed Jan. 31, 2003, effective Aug. 30, 2003. Moved to 20 CSR 2220-2.130, effective Aug. 28, 2006.*

*\*Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997 and 338.280, RSMo 1951, amended 1971, 1981.*

## **20 CSR 2220-2.140 Prescription Services by Pharmacists/Pharmacies for Residents in Long-Term Care Facilities**

*PURPOSE: This rule establishes standards for pharmacists providing prescription services to residents in long-term care facilities.*

*The standards are directed to licensed pharmacists and pharmacies, and not to long-term care facilities.*

*PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the mate-*

*rial which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. Therefore, the material which is so incorporated is on file with the agency who filed this rule, and with the Office of the Secretary of State. Any interested person may view this material at either agency's headquarters or the same will be made available at the Office of the Secretary of State at a cost not to exceed actual cost of copy reproduction. The entire text of the rule is printed here. This note refers only to the incorporated by reference material.*

(1) Licensure. A pharmacist who or pharmacy which provides prescription services to a long-term care facility must be licensed to practice pharmacy in this state. A long-term care facility means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.

(2) Medication Services.

(A) Policies and procedures shall be formulated to cover all packaging and dispensing responsibilities of the pharmacist/pharmacy to the residents of the long-term care facility and shall include, at a minimum:

1. Methods used to dispense medications in a timely fashion to the facility;

2. Proper notification to the facility when a medication is not readily available;

3. Proper labeling requirements to meet the needs of the facility and which are consistent with state and federal laws; and

4. Appropriate medication destruction, return of unused medication, or both, which is consistent with state and federal laws.

(B) Container labeling, at all times, shall conform to Chapter 338, RSMo. If a label change is required to reflect a change in directions, the pharmacist personally shall affix the correct label to the container. However, direction change labels which are defined as indicator labels that notify long-term care facility personnel that a change in directions for medication has taken place, may be used and affixed to the container by nursing home personnel in a way as not to deface the original label. Labeling of unit dose packages may be distinguished from the requirements as set forth in section 338.059, RSMo by insuring that the drug name and strength, control number and expiration date and manufacturer's name appear on the package itself. A patient's name and directions may not have to appear directly on the medication container but a mechanism should exist to identify for the personnel administering medications, what medications each patient is to receive and the directions for administration.

(C) All prescription containers, including, but not limited to, single unit, unit dose and unit-of-use containers utilized for distribution within a long-term care facility shall meet minimum requirements as referenced by the Unit-

ed States Pharmacopoeia (USP) which is incorporated herein by reference. Where applicable, light-sensitive packaging shall be used.

(3) Any drug, repackaged or prepacked that is dispensed into a long-term care facility, as defined in section (1) of this rule, in other than the manufacturer's original container, shall bear the manufacturer's expiration date or twelve (12) months, whichever is less.

(4) Remote dispensing systems are defined as any system of an automated or manual design that is used to provide doses of medication to patients for the immediate administration by authorized health care personnel and is not licensed under Chapter 338, RSMo as a pharmacy. Any medication obtained in excessive amounts shall constitute the practice of pharmacy and will require adherence to all applicable licensure and drug laws.

(A) If personnel other than a pharmacist restocks a remote dispensing system, then any drugs or other items that are to be placed within a remote dispensing system must be checked and approved by a licensed pharmacist.

(B) Any products that are repackaged for use in a remote dispensing system must comply with all provisions of 4 CSR 220-2.130.

(C) Appropriate security must be maintained over any remote dispensing system and there must be policies and procedures utilized in the delivery and storage of drugs and devices that deter misuse or theft.

(5) A prescription drug order is defined for the purpose of this rule as an order originating from a long-term care facility that is initiated by a prescriber and entered into the patient's medical record by the prescriber or qualified personnel for the purpose of initiating or renewing an order for a medication or device. All prescription drug orders shall comply with 4 CSR 220-2.018.

(A) A prescription drug order may be transferred to a licensed pharmacy for the purpose of providing an order to prepare, compound or dispense a medication or for the purpose of providing drug or medical information for use by the pharmacist in providing patient care services.

(B) In order for a generic substitution as defined in section 338.056, RSMo to take place, a prescription drug order must either comply with the prescription form as defined in section 338.056.2(1), RSMo or provide an alternate method for documenting whether a generic substitution has been authorized as determined by the long-term care medical staff. When a generic substitution is authorized and is executed by the pharmacist a clear documentation must be completed in accordance with 4 CSR 220-2.018(1)(H) and 4 CSR 220-2.080(2)(M).

(C) A pharmacy may elect to maintain a separate file system for prescription drug orders that are dispensed. When a separate file is utilized, it must comply with all applicable laws governing the maintenance and use of

a prescription file by a pharmacy and the numbering system used to number prescription drug orders must be distinct from any other prescription file that is maintained.

(D) Packaging and labeling of containers shall comply with all applicable state and federal laws for any medications that leave the facility or are provided to the patient by the pharmacy for use outside the facility. Prescription drug orders issued for use within the long-term care facility are not valid for refill outside the facility.

(6) Nothing in this rule shall be deemed to constitute a waiver or abrogation of any of the provisions of Chapter 338, RSMo or other applicable provisions of state and federal laws and rules, nor should this rule be construed as authorizing or permitting any person not licensed as a pharmacist to engage in the practice of pharmacy.

(7) The provisions of this rule are declared severable. If any portion of this rule is held invalid by a court of competent jurisdiction, the remaining provisions of this rule shall remain in full force and effect unless otherwise determined by the court.

*AUTHORITY: sections 338.010, 338.210, 338.240 and 338.280, RSMo 1994 and 338.140, RSMo Supp. 1999.\* This rule originally filed as 4 CSR 220-2.140. Original rule filed Oct. 16, 1987, effective March 25, 1988. Amended: Filed July 5, 1988, effective March 1, 1989. Amended: Filed July 19, 1991, effective Jan. 13, 1992. Amended: Filed Jan. 27, 1995, effective Sept. 30, 1995. Amended: Filed July 28, 2000, effective Jan. 30, 2001. Moved to 20 CSR 220-2.140, effective Aug. 28, 2006.*

*\*Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990; 338.140, RSMo 1939, amended 1981, 1989, 1997; 338.210, RSMo 1951; 338.240, RSMo 1951; and 338.280, RSMo 1951, amended 1971, 1981.*

## **20 CSR 220-2.145 Minimum Standards for Multi-Med Dispensing**

*PURPOSE: This rule establishes standards for multi-med dispensing.*

(1) In lieu of dispensing two (2) or more prescribed drug products in separate containers, a pharmacist may, with the consent of the patient, the patient's caregiver, or a prescriber, provide a customized patient medication package (patient med pak).

(2) A patient med pak is a package prepared by a pharmacist for a specific patient comprising one (1) or more containers and containing two (2) or more prescribed solid oral dosage forms. The patient med pak is so designed or each container is so labeled as to indicate the

day and time, or period of time, that the contents within each container are to be taken.

(A) The patient med pak shall bear a label stating—

1. The name of the patient;
2. A serial number for the patient med pak itself and a separate identifying serial number for each of the prescription orders for each of the drug products contained therein;
3. The name, strength, physical description or identification and total quantity of each drug product contained therein;
4. The directions for use and cautionary statements if any, contained in the prescription order for each drug product therein;
5. Any storage instructions or cautionary statements required by the official compendia;
6. The name of the prescriber of each drug product;
7. The date of preparation of the patient med pak and the beyond-use date assigned to the patient med pak (such beyond-use date shall be not later than sixty (60) days from the date of preparation);
8. The name, address, and telephone number of the dispenser; and
9. Any other information, statements, or warnings required for any of the drug products contained therein.

(B) If the patient med pak allows for the removal or separation of the intact containers therefrom, each individual container shall bear a label identifying each of the drug products contained therein.

(C) The patient med pak shall be accompanied by a patient package insert, in the event that any medication therein is required to be dispensed with such insert as accompanying labeling. Alternatively, such required information may be incorporated into a single, overall, educational insert provided by the pharmacist for the total patient med pak.

(D) In the absence of more stringent packaging requirements for any of the drug products contained therein, each container of the patient med pak shall comply with the moisture permeation requirements for a Class B single-unit or unit-dose container. Each container shall be either not reclosable or so designed as to show evidence of having been opened.

(E) It is the responsibility of the dispenser, when preparing a patient med pak, to take into account any applicable compendia requirements or guidelines and the physical and chemical compatibility of the dosage forms placed within each container, as well as any therapeutic incompatibilities that may attend the simultaneous administration of the medications. In this regard, pharmacists are encouraged to report to United States Pharmacopeia (USP) headquarters any observed or reported incompatibilities.

(F) In addition to any individual prescription filing requirements, a record of each patient med pak shall be made and filed. Each record shall contain, at a minimum:

1. The name and address of the patient;
2. The serial number of the prescription order for each drug product contained therein;
3. The name of the manufacturer or labeler and lot number for each drug product contained therein;
4. Information identifying or describing the design, characteristics, or specifications of the patient med pak sufficient to allow subsequent preparation of an identical patient med pak for the patient;
5. The date of preparation of the patient med pak and the beyond-use date that was assigned;
6. Any special labeling instructions; and
7. The name or initials of the pharmacist who prepared the patient med pak.

(G) There is no special exemption for patient med paks from the requirements of the Poison Prevention Packaging Act. Thus the patient med pak, if it does not meet child-resistant standards, shall be placed in an outer package that does comply, or the necessary consent of the purchaser or physician to dispense in a container not intended to be child-resistant, shall be obtained.

(H) Once a patient med pak has been delivered to an institution or to a patient it shall not be returned to the pharmacy, unless the following requirements are met:

1. The med pak is returned to the pharmacy from which it was originally dispensed;
2. The med pak is modified/repackaged, per prescription order, for the same patient to whom it was originally dispensed;
3. The med pak is labeled in compliance with the requirements of this rule, provided the med pak shall retain the original beyond-use date assigned to the med pak before modification/repackaging;
4. The med pak is assigned a new serial number;
5. The medications removed from the med pak are destroyed in compliance with state and federal law. In no event shall medication removed from a med pak be returned to stock/inventory or dispensed to another patient; and
6. Licensees shall comply with all applicable record-keeping requirements.

(I) Multi-med packaging of controlled substances is prohibited.

(J) Except as otherwise allowed in subsection (H) of this section, once a drug has been commingled with other drugs in a med pak the drug may not be returned to stock, dispensed, or distributed except for destruction purposes.

*AUTHORITY: sections 338.010 and 338.140, RSMo Supp. 2011, and section 338.059, RSMo 2000.\* This rule originally filed as 4 CSR 220-2.145. Original rule filed March 15, 2000, effective Sept. 30, 2000. Moved to 20 CSR 2220-2.145, effective Aug. 28, 2006. Amended: Filed Jan. 3, 2012, effective June 30, 2012.*

*\*Original authority: 338.010, RSMo 1939, amended*



1951, 1989, 1990, 2007, 2009, 2011; 338.059, RSMo 1971, amended 1973, 1978, 1997; and 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011.

## **20 CSR 2220-2.150 Mandatory Reporting Rule**

*PURPOSE: This rule defines the responsibilities of a director of pharmacy or the pharmacist-in-charge, or both, in a hospital or ambulatory surgical center in reporting disciplinary actions against pharmacist employees to the chief executive officer of the employing institution.*

(1) The board of pharmacy shall receive and process any report from a hospital or ambulatory surgical center concerning any disciplining action against a licensed pharmacist or the voluntary resignation of any licensed pharmacist against whom any complaints or reports have been made which might have led to final disciplinary action.

(2) Reports to the board shall comply with the minimum requirements as set forth in section 383.133, RSMo and this rule. This information shall include, but not be limited to:

(A) The name, address and telephone number of the person making the report;

(B) The name, address and telephone number of the person who is the subject of the report;

(C) A brief description of the facts which gave rise to the issuance of the report, including the dates of occurrence deemed to necessitate the filing of the report;

(D) If court action is involved and known to the reporting agent, the identity of the court, including the date of filing and the docket number of the action;

(E) A statement as to what final action was taken by the institution; and

(F) That the report is being submitted in order to comply with the reporting provisions of Chapter 383, RSMo.

(3) The director of pharmacy or pharmacist-in-charge shall report any actions as described in section (1) to the chief executive officer (CEO) or his/her designee. Any activity that is construed to be a cause for disciplinary action according to section 338.055, RSMo or results in potential or actual harm to the public shall be deemed reportable to the board. Nothing in this rule shall be construed as limiting or prohibiting any pharmacist from reporting a violation of the Pharmacy Practice Act directly to the Missouri Board of Pharmacy.

(4) In response to an inquiry from a hospital or ambulatory surgical center regarding reports received by the board on a specific pharmacist, the board shall provide the following information:

(A) Whether any reports have been received;

(B) The nature of each report; and

(C) The action which the board took on each report or if

the board has taken action on the report.

(5) Each report received shall be acknowledged in writing. The acknowledgment shall state that the report is being reviewed by the board or is being investigated and shall be referred to the board or an appropriate board subcommittee for consideration. The institution subsequently shall be informed in writing as to whether the report has been dismissed by the board or is being referred to legal counsel for filing with the Administrative Hearing Commission or for other legal action. The institution may be notified of the ultimate disposition of the report excluding judicial appeals and may be provided with a copy of the decisions (if any) of the Administrative Hearing Commission and the board.

(6) The provisions of this rule are declared severable. If any portion of this rule is held invalid by a court of competent jurisdiction, the remaining provisions of this rule shall remain in full force and effect, unless otherwise determined by a court of competent jurisdiction.

*AUTHORITY: sections 338.140, RSMo Supp. 1989 and 383.133, RSMo 1986. \* This rule originally filed as 4 CSR 220-2.150. Original rule filed Aug. 4, 1987, effective Jan. 29, 1988. Moved to 20 CSR 2220-2.150, effective Aug. 28, 2006.*

*\*Original authority: 338.140, RSMo 1939, amended 1981, 1989 and 383.133, RSMo 1986.*

## **20 CSR 2220-2.160 Definition of Disciplinary Actions**

*PURPOSE: This rule defines disciplinary actions which may be imposed by the Missouri Board of Pharmacy.*

(1) The Missouri Board of Pharmacy may publish or cause to be published all disciplines of certificates of registration or licenses or both, including the name of the licensee, the license number, the terms of discipline and a summary of the Findings of Fact and Conclusions of Law of the Administrative Hearing Commission, in any professional journal or newsletter read by licensed pharmacists practicing in Missouri or in any newspaper of general circulation or both.

(2) The Missouri Board of Pharmacy may publicize the terms of disciplinary agreements, including the name of the licensee, the license number and a summary of the complaint, in any professional journal or newsletter read by licensed pharmacists practicing in Missouri or in any newspaper of general circulation.

(3) Any licensee whose certificate of registration, license to practice pharmacy, or both, has been revoked or suspended shall—

(A) Surrender his/her certificate of registration or li-

cense, or both, to the Missouri Board of Pharmacy to be held by the Missouri Board of Pharmacy for the duration of the suspension period;

(B) Refrain from misrepresenting the status of his/her license to practice pharmacy to any patient or to the general public; and

(C) Refrain from maintaining a physical presence in any location which is licensed as a pharmacy in Missouri during the period of suspension, except as a customer.

(4) The Missouri Board of Pharmacy may impose any other terms or requirements which, in its discretion, it may deem necessary to enforce an order of discipline.

(5) Any violation of a disciplinary order shall constitute grounds for the Missouri Board of Pharmacy to impose further discipline or terms on the licensee's certificate of registration, license to practice pharmacy, or both.

(6) Any violation of a disciplinary agreement shall constitute grounds for the Missouri Board of Pharmacy to impose a further period of discipline unless the disciplinary agreement provides otherwise.

(7) If at any time when any disciplinary sanctions have been imposed under section 338.055, RSMo or under any provision, the licensee removes him/herself from Missouri, ceases to be currently licensed under the provisions of sections 338.010–338.310, RSMo or fails to keep the Missouri Board of Pharmacy advised of his/her current place of employment and residence, the time of his/her absence or unlicensed status or unknown whereabouts may, at the discretion of the board, not be deemed or taken as any part of the time of discipline so imposed.

(8) The provisions of this rule are declared severable. If any portion of this rule is held invalid by a court of competent jurisdiction, the remaining provisions of this rule shall remain in full force and effect, unless otherwise determined by a court of competent jurisdiction.

*AUTHORITY: sections 338.140, RSMo Supp. 1998 and 338.280, RSMo 1994.\* This rule originally filed as 4 CSR 220-2.160. Original rule filed Oct. 1, 1987, effective March 11, 1988. Amended: Filed June 29, 1999, effective Jan. 30, 2000. Moved to 20 CSR 2220-2.160, effective Aug. 28, 2006.*

*\*Original authority: 338.140, RSMo 1939, amended 1981, 1986 and 338.280, RSMo 1951, amended 1971, 1981.*

## **20 CSR 2220-2.165 Licensure Disciplinary Agreements**

*PURPOSE: This rule establishes guidelines to be used by the board for licensure disciplinary agreements.*

(1) The board may elect to enter into an agreement for discipline with the holder of a pharmacist or pharmacy license for the purpose of informally resolving a complaint which the board has prepared.

(2) The use of licensure disciplinary agreements shall be subject to the following:

(A) Agreements of this type will be used at the option of the board and shall not bar the board from filing any complaints with the Administrative Hearing Commission in order to seek disciplinary action for any violation of Chapter 338, RSMo;

(B) All licensure disciplinary agreements shall contain a public notice clause which provides that the board will publish the licensing action in its quarterly newsletter and shall treat the information contained in the agreement as public information;

(C) When entering into a licensure disciplinary agreement, the board and the licensee shall waive any rights attendant to a hearing before the Administrative Hearing Commission and will consent that the licensure disciplinary agreement is in lieu of proceedings before the Administrative Hearing Commission; and

(D) If the board determines that a licensee has violated a term or condition of the agreement, or has otherwise failed to comply with the provisions of Chapter 338, RSMo, which violation would be actionable in a proceeding before the State Board of Pharmacy, the Administrative Hearing Commission, or in a circuit court, the board may elect to pursue any lawful remedies or procedures afforded to it.

(3) The provisions of this rule are declared severable. If any portion of this rule is held invalid by a court of competent jurisdiction, the remaining provisions of this rule shall remain in full force and effect unless otherwise determined by a court of competent jurisdiction.

*AUTHORITY: sections 338.140, RSMo Supp. 1989 and 338.280, RSMo 1986.\* This rule originally filed as 4 CSR 220-2.165. Original rule filed Jan. 3, 1990, effective May 11, 1990. Amended: Filed July 19, 1991, effective Jan. 13, 1992. Moved to 20 CSR 2220-2.165, effective Aug. 28, 2006.*

*\*Original authority: 338.140, RSMo 1939, amended 1981, 1989 and 338.280, RSMo 1951, amended 1971, 1981.*

## **20 CSR 2220-2.170 Procedure for Impaired Pharmacist**

*PURPOSE: This rule establishes an efficient and timely process for the disposition of information and tentative board action concerning impaired pharmacists to the attorney general's office for purposes of preparing*

*a complaint and streamlines the procedure utilized in interviewing pharmacists who are chemically impaired.*

(1) The executive director shall receive information concerning the impairment of licensees and coordinate any investigations that seek to substantiate information concerning a possible impairment.

(2) Investigations by board inspectors or division investigators concerning chemically impaired licensees will be collected and reviewed by the executive director. Cases will be divided into two (2) categories.

(A) Category A. Chemically impaired licensees where additional information is evident that known distribution of controlled substances or legend drugs to other individuals has taken place.

(B) Category B. Chemical impairment of a licensee where controlled substances, legend drugs or alcohol have been acquired for personal use only.

(3) Cases which fall into Category A will be referred to the board for appropriate action.

(4) Cases which fall within Category B will be subject to administrative review as a preliminary action to facilitate any corrective actions deemed necessary by the board.

(5) The following shall constitute office procedures involving Category B cases:

(A) Normal procedures for completing field investigations and assimilating other pertinent information will be followed;

(B) If the director believes that a case falls into Category B of this policy, s/he shall consult with the president of the board concerning the appropriateness of an administrative review;

(C) If approval by the president is given, the director shall take actions necessary to set up a meeting with the licensee who is the subject of the investigation. In addition, other individuals such as legal counsel for the board may be asked to attend, along with any staff member, as necessary;

(D) A statement concerning due process procedures and the rights of the licensee will be read at the beginning of the review meeting. A complete record of the administrative review meeting shall be maintained by the board office. Notice that the president of the board has been notified and that s/he has given approval for an administrative fact-finding meeting shall be entered into the record;

(E) A format during the fact-finding meeting will be followed that allows the licensee to provide a statement of his/her own as well as a question/answer period allowed to discuss the aspects of the case centering on the chemical impairment issues or on any related concerns about the individual's ability to practice pharmacy;

(F) After the fact-finding meeting is concluded, a summary will be provided to each member of the board within the appropriate agenda, along with recommendations from the director as to any action to be taken. In

addition, the president will be contacted and provided any follow-up information that could warrant changes in administrative procedures. The president, by executive order, may initiate an affidavit to the board attorney of an intent to file a complaint with the Administrative Hearing Commission. Once an order is executed, the information on the case shall be forwarded to the attorney for necessary legal preparation; and

(G) The entire board shall consider the case in closed session as to whether or not to file a complaint against the licensee and consider the recommendations made as to terms. Once the board authorizes a complaint, the attorney for the board shall assure that the appropriate filings take place.

(6) When an impaired pharmacist is disciplined by the board and a term of the discipline is that s/he participate in a chemical dependence treatment program, the impaired pharmacist shall select a program which meets the following guidelines:

(A) Persons who are involved in the treatment or counseling of a Missouri board-licensed pharmacist must submit written documentation of their credentials and qualifications to provide treatment or counseling;

(B) A written agreement or contract must be provided and executed between the counselor(s) and the licensee, outlining the responsibilities of each party for a successful treatment and monitoring program. The agreement must include a provision for sharing information concerning all aspects of therapy between the treatment facility or counselors, or both, and the Missouri Board of Pharmacy;

(C) An initial evaluation report must be completed and provided to the board outlining the licensee's present state of impairment, the recommended course(s) of treatment, the beginning date of treatment and an assessment of future prospects for recovery;

(D) A copy of the proposed treatment plan must be provided to the board and must include a provision outlining the method of referral to an appropriate after-care program;

(E) The counselor(s) must provide progress reports to the board as follows:

1. Inpatient therapy—monthly reports;
2. Outpatient therapy—quarterly reports; and
3. After-care programs—semiannual reports;

(F) The treatment program must include randomized and witnessed body fluid testing and analysis, with any drug presence not supported by a valid prescription to be reported to the Missouri Board of Pharmacy;

(G) The treatment program must include a provision for reporting any violation of the treatment contract or agreement by the licensee to the board; and

(H) All reports outlined in this protocol must be provided in writing to the board for a counselor or treatment facility, or both, to be approved for the treatment of a licensee undergoing disciplinary board action.

*AUTHORITY: sections 338.140, RSMo Supp. 1989 and 338.240, RSMo 1986.\* This rule originally filed as 4*

CSR 220-2.170. Original rule filed Oct. 1, 1987, effective Jan. 14, 1988. Amended: Filed Nov. 15, 1988, effective March 11, 1989. Moved to 20 CSR 2220-2.170, effective Aug. 28, 2006.

\*Original authority: 338.140, RSMo 1939, amended 1981, 1989 and 338.240, RSMo 1951.

## 20 CSR 2220-2.175 Well-Being Program

**PURPOSE:** This rule establishes guidelines for the operation of the Well-Being Committee, pursuant to section 338.380, RSMo.

### (1) Definitions.

(A) Board—State Board of Pharmacy.

(B) Committee administrator—The person who is hired by the contractor or the committee to oversee and manage the Well-Being Program.

(C) Contractor—An entity with whom the board contracts for the purpose of creating, supporting, and maintaining the Well-Being Program.

(D) Impairment—An illness, substance abuse, or physical or mental condition suffered by a licensee that is reasonably related to the ability to practice pharmacy.

(E) Licensee—Pharmacist, intern pharmacist, or technician licensed or registered in the state of Missouri or who has applied for licensure or registration in the state of Missouri.

(F) Well-Being Committee—The committee established pursuant to section 338.380, RSMo, for the purpose of promoting the early identification, intervention, treatment, and rehabilitation of pharmacists, intern pharmacists, and technicians who may be impaired by reasons of illness, substance abuse, or as a result of any physical or mental condition.

(G) Well-Being Program—The activities and functions of the Well-Being Committee.

(2) The board may contract with a contractor for purposes of creating, supporting, and maintaining the Well-Being Program. The Well-Being Committee may assist the board in the identification, selection, and evaluation of the contractor, as requested by the board. Operational costs of the Well-Being Program may be paid by the board, subject to available funding. All costs of drug screens and professional and administrative services provided to a licensee shall be paid by the licensee.

### (3) Membership and Organization.

(A) The Well-Being Committee (hereinafter committee) shall be composed of the committee administrator and three (3) appointed members as follows:

1. One (1) member designated by the Missouri Pharmacy Association;

2. One (1) member designated by the Missouri Society of Health-System Pharmacists; and

3. One (1) member designated by the State Board of Pharmacy.

(B) The appointed committee members shall serve staggered three (3)-year terms and may serve as many terms as their respective organizations deem appropriate. The entity designating a member to the committee shall designate a person to finish the three (3)-year term of any member of the committee who becomes unable to serve.

(C) The committee shall annually elect a chairperson.

(D) The committee shall meet at least two (2) times annually.

(E) The appointed committee members shall serve without compensation other than that allowed by law for service as a board member. Each appointed committee member shall be entitled to reimbursement for travel expenses as deemed appropriate by the board.

(F) The committee administrator shall be a nonvoting member of the committee.

(4) An impaired licensee may enter the Well-Being Program voluntarily or by referral of the board pursuant to a settlement agreement or other disciplinary order. Licensees entering the Well-Being Program voluntarily shall be subject to and shall comply with all requirements of this rule.

### (5) Well-Being Committee Duties.

(A) The committee shall oversee all aspects of the general operation of the contractor including, but not limited to, oversight of the administration, staffing, financial operations, and case management of the Well-Being Program.

(B) The committee shall assist the board in monitoring the impaired licensee's compliance with the terms of any disciplinary order/agreement.

(C) The committee shall provide the board access to all information and documents pertaining to impaired licensees referred to the Well-Being Program by the board.

(D) The committee shall enter into written contracts with each impaired licensee. The contract between the committee and the impaired licensee shall be a minimum of five (5) years in duration, or the time designated by the board. The contract between the committee and impaired licensee shall include, but shall not be limited to, the following conditions/requirements:

1. Each impaired licensee shall comply with all terms, conditions, or treatment identified, required, or recommended by the contractor or the board for the treatment, evaluation, monitoring, or assessment of the impaired licensee;

2. Each impaired licensee shall abstain from the possession or consumption of legend medication, except as prescribed by a treating prescriber;

3. Each impaired licensee shall abstain from illegal possession of alcohol, the consumption of alcohol, and

the possession or consumption of illegal drugs;

4. Each impaired licensee shall submit to random drug testing unless otherwise specified by the board, committee, or contractor;

5. Each impaired licensee shall report to the committee or the contractor all relapses or other breaches of the contractual terms;

6. Each impaired licensee shall report to or meet with the board, committee, contractor, or the contractor's appointed designee as may be requested by the board, committee, or contractor;

7. Each impaired licensee shall attend support meetings as requested by the committee, contractor, or treatment providers;

8. Each impaired licensee referred to the Well-Being Program by the board shall authorize the committee to release any and all information regarding the impaired licensee to the board;

9. Each impaired licensee voluntarily enrolled in the Well-Being Program shall authorize the committee to release any and all information regarding the impaired licensee to the board upon a violation of any state or federal drug law or if the licensee breaches or fails to comply with any terms of a Well-Being contract; and

10. Each impaired licensee shall be financially responsible for all drug screens and any other professional or administrative service rendered on behalf of the impaired licensee.

(E) The committee shall provide to the board in writing:

1. An annual action plan and budget to be approved by the board. The committee shall report on progress with regard to preparing and implementing the action plan and budget as requested by the board or committee;

2. Progress reports with regard to each licensee participating in or being assisted by the Well-Being Program. The identity of licensees who voluntarily submit to the Well-Being Program shall remain anonymous to the board for purposes of these reports, except as otherwise provided by this rule. Progress reports shall be provided to the board at board meetings or upon request of the board;

3. Except as otherwise provided by this rule for voluntary participants, any and all information or documentation with regard to the identification, intervention, treatment, and rehabilitation of any licensee who participates in, or is assisted by, the Well-Being Program;

4. Quarterly income and expense reports. These reports must be itemized and account for all income from any and every source and each expense to any and every vendor that relates to the Well-Being Program in any way; and

5. Any other report or information requested by the board, except as otherwise provided by this rule for voluntary participants.

(F) In addition to the other requirements of this rule, the committee shall also report, in writing, to the board:

1. All licensee violations of board disciplinary orders/

agreements, board statutes or regulations, or other state or federal drug laws which occur after the date of the disciplinary order/agreement or the date the licensee entered the Well-Being Program, whichever occurs first;

2. Any licensee who fails to enter treatment within forty-eight (48) hours following the provider's determination that the licensee needs treatment;

3. Any licensee who does not comply with the terms of a Well-Being Program contract or who resumes the practice of pharmacy before the treatment provider has made a clear determination that the licensee is capable of practicing; and

4. Any breach of contract by the Well-Being Committee or the committee administrator.

(G) The identity of licensees who voluntarily submit to the Well-Being Program shall remain anonymous to the board, provided that upon receipt of a Notice of Non-Compliance from the contractor, the committee shall promptly file a complaint with the board against the licensee identified in the notice. The complaint required by this subsection shall include the impaired licensee's name, license number, and the factual basis for the alleged contractual breach/non-compliance. Upon the filing of a complaint, the committee shall require the committee administrator to supply to the board any information or documentation with regard to the licensee's identification, intervention, treatment, compliance, and rehabilitation, as requested by the board or their designated representative.

(H) The committee shall require the costs of drug screens and professional and administrative services to be paid by the impaired licensee.

#### (6) Committee Administrator Duties.

(A) The committee administrator shall oversee and manage the daily operations of the committee and assist with the administrative duties of the committee.

(B) The committee administrator shall possess a combination of education and experience in the area of addiction counseling and be currently licensed in Missouri as a psychologist, psychiatrist, professional counselor, or clinical social worker. Upon request of the committee, the board may waive the licensure requirements of this subsection for qualified applicants that otherwise possess an equivalent combination of education and experience, as required by this rule.

(C) The committee administrator shall also be familiar with licensees suffering from impairment issues which include, but shall not be limited to, the following:

1. Dependency;
2. Alcohol addiction;
3. Drug addiction;
4. Other addictive diseases;
5. Physical issues; and
6. Mental health issues.

(D) Upon referral, the duties of the committee administrator shall also include, but are not limited to, assisting

the committee with the following:

1. Organizing and carrying out interventions;
2. Referring licensees for appropriate assessment or evaluation and seeing that treatment recommendations based on the assessment are followed;
3. Monitoring treatment progress and re-entry contractual compliance;
4. Managing/monitoring random drug screens;
5. Assisting licensees to re-enter practice from treatment;
6. Assisting with aftercare issues;
7. Any and all reporting to appropriate agencies, as requested by the board or the committee;
8. Program development;
9. Outreach education, as requested by the committee; and
10. Other necessary services as determined by the committee.

(E) Upon request by the committee, the committee administrator shall supply to the committee in writing:

1. Any information or documentation regarding the operation of the Well-Being Program;
2. All information or documentation with regard to the identification, intervention, treatment, and rehabilitation of any licensee that is participating in or being assisted by the Well-Being Program or who has participated in or been assisted by the Well-Being Program;
3. Progress reports to the committee with regard to each licensee participating in the Well-Being Program; and
4. Any reports provided to the board.

(F) Upon request, the committee administrator shall supply to the board in writing:

1. Any information requested by the board regarding the Well-Being Program or any licensee participating in or being assisted by the Well-Being Program, except as otherwise provided herein for voluntary participants; and
2. Any information or documentation with regard to the identification, intervention, treatment, rehabilitation, and compliance of any voluntary participant who breaches or fails to comply with the terms of any Well-Being Program contract or violates any state or federal law.

#### (7) Contractor Duties.

(A) Upon referral, the contractor shall be responsible for requiring evaluators to provide written reports which address whether a participant of the Well-Being Program suffers from an impairment, identifies the impairment, provides recommendations for treatment of the impairment, and whether the participant's practice of pharmacy should be restricted due to the impairment; and

(B) The contractor shall provide services when appropriate to impaired licensees which include, but are not limited to, the following:

1. Monitoring compliance of the contract between the committee and the impaired licensee;
2. Assisting the impaired licensee in obtaining evalua-

tion and treatment;

3. Ensuring that treatment recommendations based on the assessment of the licensee are followed;
4. Monitoring treatment progress and re-entry contractual compliance;
5. Managing/monitoring random drug screens;
6. Assisting licensees to re-enter practice from treatment;
7. Assisting with aftercare issues;
8. Any and all reporting to appropriate agencies, as requested by the board or the committee;
9. Program development;
10. Outreach education, as requested by the committee;
11. Managing, ensuring, and monitoring random and scheduled drug screens; and
12. Other necessary services as determined by the committee.

(C) The contractor shall assist the board in monitoring the impaired licensee's compliance with the terms of any disciplinary order/agreement.

(D) The contractor shall obtain a written release from all licensees referred to the Well-Being Program that authorizes the contractor to release to the board, the committee, or the committee administrator all information and documents pertaining to a licensee referred by the board.

(E) Voluntary Participants.

1. Except as otherwise provided in this subsection, the identity of licensees who voluntarily submit to the Well-Being Program shall remain anonymous to the board.

2. The contractor shall file with the committee a Notice of Non-Compliance against any voluntary participant who breaches or fails to comply with the terms of any Well-Being Program contract or who violates any state or federal drug law. If a complaint is filed by the committee against the licensee, the contractor shall require the committee administrator to supply to the board any information or documentation with regard to the licensee's identification, intervention, treatment, compliance, and rehabilitation, as requested by the board.

3. The contractor shall obtain a written release from all licensees who voluntarily enter the Well-Being Program that authorizes the contractor to release any and all information or documents pertaining to the licensee to the board or the committee in the event the licensee breaches or fails to comply with the terms of any Well-Being Program contract or violates any state or federal drug law.

(F) General Reporting.

1. The contractor shall provide to the committee in writing:

A. An annual action plan and budget to be approved by the board. The contractor shall report on progress with regard to preparing and implementing the action plan and budget as requested by the board or committee;

B. Quarterly income and expense reports for the Well-Being Program and any other financial report requested by the board or the committee;

C. Progress reports with regard to each licensee participating in or being assisted by the Well-Being Program;

D. Any reports provided to the board;

E. Any and all information or documentation with regard to the identification, intervention, treatment, and rehabilitation of any licensee who participates in, or is assisted by, the Well-Being Program;

F. Any other report or information requested by the committee; and

G. The information and documentation required by this subsection shall only be released to the board pursuant to Chapter 338, RSMo, and the rules promulgated thereto.

2. The contractor shall provide to the board in writing:

A. An annual action plan and budget as directed by the board. The contractor shall report on progress with regard to preparing and implementing the action plan and budget as requested by the board or committee;

B. Progress reports with regard to each licensee participating in or being assisted by the Well-Being Program, provided the identity of licensees who voluntarily submit to the Well-Being Program shall remain anonymous to the board for purposes of these reports, except as otherwise provided by this rule; and

C. Any other report or information requested by the board, except as otherwise provided by this rule for voluntary participants.

(G) Violation Reporting. In addition to the other requirements of this rule, the contractor shall report, in writing, to the committee:

1. All licensee violations of a board disciplinary order/agreement, any provision of Chapter 338, RSMo, or the board regulations, or any state or federal drug law, which occurs after the date of the disciplinary order/agreement or the date the licensee entered the Well-Being Program, whichever occurs first;

2. Any licensee who fails to enter treatment within forty-eight (48) hours following the provider's determination that the licensee needs treatment; and

3. Any licensee who does not comply with the terms of a Well-Being Program contract or who resumes the practice of pharmacy before the treatment provider has made a clear determination that the licensee is capable of practicing.

(H) The contractor shall require the costs of drug screens and professional and administrative services to be paid by the impaired licensee.

(8) Confidentiality.

(A) The committee and contractor shall provide the board access to all information pertaining to each impaired licensee referred to the committee by the board.

(B) In regards to participants referred by the board and

the voluntary participants who have violated or breached their Well-Being Program contracts, the board and committee may exchange privileged and confidential information, interviews, reports, statements, memoranda, and other documents including information on investigations, findings, conclusions, interventions, treatment, rehabilitation, and other proceedings of the board and committee, and other information closed to the public to promote the identification, interventions, treatment, rehabilitation, and discipline (accountability) of licensees who may be impaired.

(C) All privileged and confidential information and other information not considered to be public records or information pursuant to Chapter 610, RSMo, shall remain privileged and confidential and closed to the public after such information is exchanged.

*AUTHORITY: section 338.140.1, RSMo 2000 and section 338.380, RSMo Supp. 2009.\* Original rule filed Aug. 18, 2009, effective March 30, 2010.*

*\*Original authority: 338.140.1, RSMo 1939, amended 1981, 1989, 1997 and 338.380, RSMo 2007.*

## **20 CSR 2220-2.180 Public Records**

*PURPOSE: This rule establishes standards for compliance with Chapter 610, RSMo as it relates to public records of the State Board of Pharmacy.*

(1) All public records of the State Board of Pharmacy shall be open for inspection and copying by any member of the general public during normal business hours, holidays excepted, except for those records closed pursuant to section 610.021, RSMo. All public meetings of the Board of Pharmacy not closed pursuant to the provisions of section 610.021, RSMo will be open to any member of the public.

(2) The Board of Pharmacy establishes the executive director of the board as the custodian of its records as required by section 610.023, RSMo. The executive director is responsible for the maintenance of the board's records and is responsible for responding to requests for access to public records.

(3) When a request for inspection of public records is made and the individual inspecting the records requests copies of the records, the board will collect the appropriate fee for costs for inspecting and copying of the records, as outlined in the board's fee rule, 4 CSR 220-4.020. The board may require payment of the fees prior to making available any public records.

(4) When a request for access to public records is made and the custodian believes that access is not required under the provisions of Chapter 610, RSMo, the custo-

dian shall inform the individual or entity making the request that compliance with the request cannot be made, specifying in particular what sections of Chapter 610, RSMo require that the record remain closed. Any such correspondence or documentation of the denial made for access to records shall be copied to the Board of Pharmacy general counsel. Whenever the custodian denies access to the records, the custodian also shall inform the individual requesting the records that s/he may appeal directly to the Board of Pharmacy for access to the records requested. The appeal and all information pertaining to the appeal shall be placed on the meeting agenda of the Board of Pharmacy for its next regularly scheduled meeting. In the event that the board decides to reverse the decision of the custodian, the board shall direct the custodian to so advise the person requesting access to the information and supply the access to the information during regular business hours at the convenience of the requesting party.

(5) The custodian shall maintain a file which will contain copies of all written requests for access to records and responses to the requests. These requests shall be maintained on file with the board for a period of one (1) year and will be maintained as a public record of the board open for inspection by any member of the general public during regular business hours.

(6) Pursuant to section 620.111, RSMo any complaints, investigation reports and accompanying documents or exhibits that are considered closed documents under Chapter 610 or 620, RSMo, and are possessed by the board or any of its agents shall not be disclosed to any member of the public or to a licensee until the investigation is completed.

(A) Federal or state agency documents shall not be released without the written consent of the federal or state agency involved.

*AUTHORITY: sections 338.140, 338.280, Chapters 610 and 620, RSMo 1994.\* This rule originally filed as 4 CSR 220-2.180. Original rule filed Jan. 19, 1988, effective April 28, 1988. Amended: Filed June 26, 1995, effective Feb. 25, 1996. Moved to 20 CSR 2220-2.180, effective Aug. 28, 2006.*

*\*Original authority: 338.140, RSMo 1939, amended 1981, 1989 and 338.280, RSMo 1951, amended 1971, 1981. For Chapters 610 and 620, please consult the Missouri Revised Statutes.*

## **20 CSR 2220-2.190 Patient Counseling**

*PURPOSE: This rule establishes minimum standards for patient counseling to comply with the federal Omnibus Budget Reconciliation Act of 1990 which requires that all states establish standards by January 1, 1993.*

(1) Upon receipt of a prescription drug order and follow-

ing a review of the available patient information, a pharmacist or his/her designee shall personally offer to discuss matters which will enhance or optimize drug therapy with each patient or caregiver of each patient. Counseling shall be conducted by the pharmacist or a pharmacy extern under the pharmacist's immediate supervision to allow the patient to safely and appropriately utilize the medication so that maximum therapeutic outcomes can be obtained. If the patient or caregiver is not available, then a written offer to counsel with a telephone number of the dispensing pharmacy at no cost to the patient must be supplied with the medication so that the patient or caregiver may contact the pharmacist for counseling when necessary. In situations where automated pick-up systems are used for providing refill prescriptions to patients, the offer to counsel may be provided within the information provided by the kiosk to the patient during the processing phase prior to release of the medication to the patient. The elements of counseling shall include matters which the pharmacist deems significant in the exercise of his/her professional judgment and is consistent with applicable state laws.

(2) Pharmacies shall maintain appropriate patient information to facilitate counseling. This may include, but shall not be limited to, the patient's name, address, telephone number, age, gender, clinical information, disease states, allergies and a listing of other drugs prescribed.

(3) Alternative forms of patient information shall be used to supplement patient counseling when appropriate. Examples may include, but shall not be limited to, written information leaflets, pictogram labels, video programs, and the like.

(4) Patient counseling, as described in this rule, shall not be required for inpatients of a hospital, institution or other setting where other licensed or certified health care professionals are authorized to administer medications.

(5) A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses consultation.

*AUTHORITY: sections 338.140 and 338.280, RSMo 2000.\* This rule originally filed as 4 CSR 220-2.190. Original rule filed May 1, 1992, effective Feb. 26, 1993. Amended: Filed March 4, 1993, effective Oct. 10, 1993. Moved to 20 CSR 2220-2.190, effective Aug. 28, 2006. Amended: Filed Aug. 21, 2006, effective April 30, 2007.*

*\*Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997 and 338.280, RSMo 1951, amended 1971, 1981.*



## 20 CSR 2220-2.200 Sterile Pharmaceuticals

**PURPOSE:** *This rule establishes standards for the preparation, labeling and distribution of sterile pharmaceuticals by licensed pharmacies, pursuant to a physician's order or prescription.*

### (1) Definitions.

(A) Aseptic processing: The technique involving procedures designed to preclude contamination of drugs, packaging, equipment, or supplies by microorganisms during processing.

(B) Batch: Compounding of multiple sterile product units in a single discrete process, by the same individuals, carried out during one (1) limited time period.

(C) Beyond-Use date: A date after which a compounded preparation should not be used and is determined from the date the preparation is compounded. Because compounded preparations are intended for administration immediately or following short-term storage, their beyond-use dates must be assigned based on criteria different from those applied to assigning expiration dates to manufactured drug products.

(D) Biological safety cabinet: Containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel and environment, according to National Sanitation Foundation (NSF) International standards.

(E) Class 100 environment: An atmospheric environment which contains less than one hundred (100) particles 0.5 microns in diameter per cubic foot of air, according to federal standards.

(F) Class 10,000 environment: An atmospheric environment which contains less than ten thousand (10,000) particles 0.5 microns in diameter per cubic foot of air, according to federal standards.

(G) Clean room: A room—

1. In which the concentration of airborne particles is controlled;

2. That is constructed and used in a manner to minimize the introduction, generation, and retention of particles inside the room; and

3. In which other relevant variables (e.g., temperature, humidity, and pressure) are controlled as necessary.

(H) Clean zone: Dedicated space—

1. In which the concentration of airborne particles is controlled;

2. That is constructed and used in a manner that minimizes the introduction, generation, and retention of particles inside the zone; and

3. In which other relevant variables (e.g., temperature, humidity, and pressure) are controlled as necessary.

This zone may be open or enclosed and may or may not be located within a clean room.

(I) Compounding: For the purposes of this regulation, compounding is defined as in 20 CSR 2220-2.400(1). Compounded sterile medications may include, but are

not limited to, injectables, parenteral nutrition solutions, irrigation solutions, inhalation solutions, intravenous solutions and ophthalmic preparations.

(J) Controlled area: For purposes of these regulations, a controlled area is the area designated for preparing sterile products. This is referred to as the buffer zone (i.e., the clean room in which the laminar airflow workbench is located) by the United States Pharmacopoeia (USP).

(K) Critical area: Any area in the controlled area where products or containers are exposed to the environment.

(L) Critical site: An opening providing a direct pathway between a sterile product and the environment or any surface coming into contact with the product or environment.

(M) Critical surface: Any surface that comes into contact with previously sterilized products or containers.

(N) Cytotoxic drugs: A pharmaceutical product that has the capability of direct toxic action on living tissue that can result in severe leukopenia and thrombocytopenia, depression of the immune system and the alteration of a host's inflammatory response system.

(O) Emergency dispensing: Is a situation where a Risk Level 3 product is necessary for immediate administration of the product and no alternative product is available and the prescriber is informed that the product is being dispensed prior to appropriate testing. Documentation of the dispensing of the product, the prescriber's approval for dispensing prior to the receipt of test results and the need for the emergency must appear within the prescription record. A separate authorization from the prescriber is required for each emergency dispensing.

(P) High-Efficiency Particulate Air (HEPA) filter: A filter composed of pleats of filter medium separated by rigid sheets of corrugated paper or aluminum foil that direct the flow of air forced through the filter in a uniform parallel flow. HEPA filters remove ninety-nine point ninety-seven percent (99.97%) of all particles three-tenths (0.3) microns or larger. When HEPA filters are used as a component of a horizontal- or vertical-laminar-airflow workbench, an environment can be created consistent with standards for a Class 100 clean room.

(Q) Isolator (or barrier isolator): A closed system made up of four (4) solid walls, an air-handling system, and transfer and interaction devices. The walls are constructed so as to provide surfaces that are cleanable with coving between wall junctures. The air-handling system provides HEPA filtration of inlet air. Transfer of materials is accomplished through air locks, glove rings, or ports. Transfers are designed to minimize the entry of contamination. Manipulations can take place through either glove ports or half suits.

(R) Parenteral: A sterile preparation of drugs for injection through one (1) or more layers of skin.

(S) Process validation or simulation: Microbiological simulation of an aseptic process with growth medium processed in a manner similar to the processing of the

product and with the same container or closure system.

(T) Quality assurance: For purposes of these regulations, quality assurance is the set of activities used to ensure that the processes used in the preparation of sterile drug products lead to products that meet predetermined standards of quality.

(U) Quality control: For the purposes of these regulations, quality control is the set of testing activities used to determine that the ingredients, components and final sterile products prepared meet predetermined requirements with respect to identity, purity, nonpyrogenicity and sterility.

(V) Repackaging: The subdivision or transfer of a compounded product from one container or device to a different container or device.

(W) Sterile pharmaceutical: A dosage form free from living microorganisms.

(X) Sterilization: A validated process used to render a product free of viable organisms.

(Y) Temperatures:

1. Frozen means temperatures between twenty below zero and ten degrees Celsius (20 and 10°C) (four below zero and fourteen degrees Fahrenheit (4 and 14°F)).

2. Refrigerated means temperatures between two and eight degrees Celsius (2 and 8°C) (thirty-six and forty-six degrees Fahrenheit (36 and 46°F)).

3. Room temperatures means room temperatures between fifteen and thirty degrees Celsius (15 and 30°C) (fifty-nine and eighty-six degrees Fahrenheit (59 and 86°F)).

(Z) Validation: Documented evidence providing a high degree of assurance that specific processes will consistently produce a product meeting predetermined specifications and quality attributes.

(AA) Definitions of sterile compounded products by risk level:

1. Risk Level 1: Applies to compounded sterile products that exhibit characteristics A., B., and C., stated below. All Risk Level 1 products shall be prepared with sterile equipment, sterile ingredients and solutions and sterile contact surfaces for the final product. Risk Level 1 includes the following:

A. Products:

(I) Stored at room temperature and completely administered within forty-eight (48) hours after preparation; or

(II) Stored under refrigeration for seven (7) days or less before complete administration to a patient over a period not to exceed forty-eight (48) hours; or

(III) Frozen for thirty (30) days or less before complete administration to a patient over a period not to exceed forty-eight (48) hours.

B. Unpreserved sterile products prepared for administration to one (1) patient or batch-prepared products containing suitable preservatives prepared for administration to more than one (1) patient.

C. Products prepared by closed-system aseptic

transfer of sterile, nonpyrogenic, finished pharmaceuticals (e.g., from vials or ampules) obtained from licensed manufacturers into sterile final containers obtained from licensed manufacturers.

2. Risk Level 2: Sterile products exhibit characteristic A., B., or C., stated below. All Risk Level 2 products shall be prepared with sterile equipment, sterile ingredients and solutions and sterile contact surfaces for the final product and with closed-system transfer methods. Risk Level 2 includes the following:

A. Products stored beyond seven (7) days under refrigeration, stored beyond thirty (30) days frozen or administered beyond forty-eight (48) hours after preparation and storage at room temperature.

B. Batch-prepared products without preservatives that are intended for use by more than one (1) patient.

C. Products compounded by complex or numerous manipulations of sterile ingredients obtained from licensed manufacturers in a sterile container or reservoir obtained from a licensed manufacturer by using closed-system aseptic transfer (e.g., automated compounder).

3. Risk Level 3: Sterile products exhibit either characteristic A. or B.:

A. Products compounded from nonsterile ingredients or compounded with nonsterile components, containers or equipment before terminal sterilization.

B. Products prepared by combining multiple ingredients (sterile or nonsterile) by using an open-system transfer or open reservoir before terminal sterilization.

(2) Policy and Procedure Manual/Reference Manuals.

(A) A manual, outlining policies and procedures encompassing all aspects of Risk Level 1, 2 and 3 products, shall be available for inspection at the pharmacy. The manual shall be reviewed on an annual basis. The pharmacy shall have current reference materials related to sterile products.

(3) Personnel Education, Training and Evaluation.

(A) Risk Level 1: All pharmacy personnel preparing sterile products must receive suitable didactic and experiential training.

(B) Risk Level 2: In addition to Risk Level 1 requirements, personnel training includes assessment of competency in all Risk Level 2 procedures via process simulation.

(C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, operators have specific education, training and experience to prepare Risk Level 3 products. The pharmacist knows principles of good compounding practice for risk level products, including—

1. Aseptic processing;

2. Quality assurance of environmental, component, and end-product testing;

3. Sterilization; and

4. Selection and use of containers, equipment, and closures.

#### (4) Storage and Handling in the Pharmacy.

(A) Risk Level 1 and 2: Solutions, drugs, supplies and equipment must be stored according to manufacturer or USP requirements. Refrigeration and freezer temperatures shall be documented daily. Other storage areas shall be inspected regularly to ensure that temperature and lighting meet requirements. Drugs and supplies shall be shelved above the floor. Removal of products from boxes shall be done outside controlled areas. Removal of used supplies from the controlled area shall be done at least daily. Product recall procedures must permit retrieving affected products from specific involved patients.

(B) Risk Level 3: In addition to Risk Level 1 and 2 requirements, procedures include procurement, identification, storage, handling, testing, and recall of components and finished products. Finished but untested Risk Level 3 products must be quarantined under minimal risk for contamination.

#### (5) Facilities and Equipment.

(A) Risk Level 1: The controlled area shall be separated from other operations. The controlled area must be clean and well lit. A sink with hot and cold water must be near, but not in, the controlled area. The controlled area and inside equipment must be cleaned and disinfected regularly. Sterile products must be prepared in at least a Class 100 environment (the critical area). Computer entry, order processing, label generation, and record keeping shall be performed outside the critical area. The critical area must be disinfected prior to use. A workbench shall be recertified every six (6) months and when it is moved; prefilters must be visually inspected on a regularly scheduled basis and replaced according to manufacturer's specifications. Pumps utilized in the compounding process shall be recalibrated and documented according to manufacturer procedures.

(B) Risk Level 2: In addition to all Risk Level 1 requirements, the controlled area must meet Class 10,000 clean room standards; cleaning supplies should be selected to meet clean room standards; critical area work surface must be cleaned between batches; floors should be disinfected daily; equipment surfaces weekly; and walls monthly; with applicable environmental monitoring of air and surfaces. Automated compounding devices must be calibrated and verified as to accuracy, according to manufacturer procedures. Clean rooms not utilized on a daily basis must be cleaned prior to use as stated above.

(C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, products must be prepared in a Class 100 workbench in a Class 10,000 clean room, in a Class 100 clean room or within a positive pressure barrier isolator. Access to the clean room must be limited to those preparing the products and who are in appropriate garb. Equipment must be cleaned, prepared, sterilized, calibrated, and documented according to manufacturer's

standards. Walls and ceilings must be disinfected weekly. All non-sterile equipment that is to come in contact with the sterilized final product must be sterilized before introduction in the clean room. Appropriate cleaning and disinfection of the environment and equipment are required.

#### (6) Apparel.

(A) Risk Level 2: In the controlled area, personnel wear low particulate, clean clothing covers. Head and facial hair is covered. Gloves, gowns, and masks are required. During sterile preparation gloves shall be rinsed frequently with a suitable agent and changed when integrity is compromised.

(B) Risk Level 3: In addition to Risk Level 2 requirements, clean room apparel must be worn inside the controlled area at all times during the preparation of Risk Level 3 sterile products except when positive pressure barrier isolation is utilized. Attire shall consist of a low-shedding coverall, head cover, face mask, and shoe covers.

#### (7) Aseptic Technique and Product Preparation.

(A) Risk Level 1: Sterile products must be prepared in a Class 100 environment. Personnel shall scrub their hands and forearms for an appropriate period at the beginning of each aseptic compounding process. Eating, drinking and smoking are prohibited in the controlled area. Talking shall be minimized to reduce airborne particles. Ingredients shall be determined to be stable, compatible, and appropriate for the product to be prepared, according to manufacturer, USP, or scientific references. Ingredients and containers shall be inspected for defects, expiration and integrity before use. Only materials essential for aseptic compounding shall be placed in the workbench. Surfaces of ampules and vials shall be disinfected before placement in the workbench. Sterile components shall be arranged in the workbench to allow uninterrupted laminar airflow over critical surfaces of needles, vials, ampules, etc. Automated devices and equipment shall be cleaned, disinfected and placed in the workbench to enable laminar airflow. Aseptic technique shall be used to avoid touch contamination of critical sites of containers and ingredients. Particles shall be filtered from solutions. Needle cores shall be avoided. The pharmacist shall check before, during, and after preparation to verify the identity and amount of ingredients before release.

(B) Risk Level 2: In addition to Risk Level 1 requirements, a file containing formula, components, procedures, sample label, and final evaluation shall be made for each product batch. A separate work sheet and lot number for each batch shall be completed. When combining multiple sterile products, a second verification of calculations shall take place. The pharmacist shall verify data entered into any automatic compounder before processing and check the end product for accuracy.

(C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, nonsterile components must meet standards if available, as verified by a pharmacist and a certificate of analysis. Batch preparation files shall also include comparisons of actual with anticipated yields, sterilization methods, and quarantine specifications. Presterilized containers shall be used when feasible. Final containers must be sterile and capable of maintaining product integrity throughout the shelf life. Sterilization methods must be based on properties of the product.

(8) Process Validation.

(A) Risk Level 1: All pharmacy personnel who prepare sterile products shall pass a process validation of aseptic technique before compounding sterile products. Pharmacy personnel competency must be reevaluated by process validation at least annually, whenever the quality assurance program yields an unacceptable result, or whenever unacceptable techniques are observed. If microbial growth is detected, the entire sterile process must be evaluated, corrective action taken, and the process simulation test performed again.

(B) Risk Level 2: In addition to Risk Level 1 requirements, process simulation procedures shall cover all types of manipulations, products and batch sizes.

(C) Risk Level 3: In addition to all Risk Level 1 and 2 requirements, written policies shall be maintained to validate all processes, procedures, components, equipment and techniques.

(9) Record Keeping.

(A) Risk Level 1: The following must be documented:

1. Training and competency evaluation of pharmacy personnel involved in sterile product preparation;
2. Refrigerator and freezer temperature logs;
3. Certification of workbenches;
4. Copies of any manufacturer standards that are relied upon to maintain compliance with this rule; and
5. Other facility quality control logs as appropriate including all maintenance, cleaning, and calibration records.

(B) Risk Level 2: In addition to Risk Level 1 requirements, records of any end-product testing and batch preparation records must be maintained.

(C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, record requirements for Risk Level 3 products must include:

1. Preparation work sheet;
2. Sterilization records;
3. Quarantine records, if applicable;
4. End-product evaluation and testing records as required in section (12); and
5. Ingredient validation records as required in section (12).

(D) All records and reports shall be maintained for two (2) years and shall be readily retrievable, subject to inspections by the board of pharmacy or its agents.

(10) Labeling.

(A) Risk Level 1: Sterile products dispensed to patients shall be labeled in accordance with section 338.059, RSMo and with the following supplemental information affixed to a permanent label:

1. Beyond-use date;
2. Storage requirements;
3. Any device specific instructions; and
4. Auxiliary labels, when applicable.

(B) Risk Level 2: All requirements for Risk Level 1 must be met.

(C) Risk Level 3: All requirements for Risk Level 1 must be met.

(11) Beyond-Use Dating.

(A) Risk Level 1: All sterile products must bear a beyond-use date. Beyond-use dates are assigned based on current drug stability information and sterility considerations.

(B) Risk Level 2: All requirements for Risk Level 1 must be met.

(C) Risk Level 3: In addition to all Risk Level 1 requirements, there must be a reliable method for establishing all expiration dates, including laboratory testing of product stability, pyrogenicity, particulate contamination and potency. Expiration dating not specifically referenced in the product's approved labeling or not established by product specific instrumental analysis, shall be limited to thirty (30) days. Beyond-use dating not specifically referenced in the products approved labeling or not established by product specific instrumental analysis shall be limited to thirty (30) days. There must be a reliable method for establishing all beyond-use dating. Products maintaining beyond-use dating of greater than thirty (30) days shall have lab testing of product stability and potency.

(12) End-Product Evaluation.

(A) Risk Level 1: The final product must be inspected for container leaks, integrity, solution cloudiness or phase separation, particulates in solution, appropriate solution color, and solution volume. The pharmacist must verify that the product was compounded accurately as to the ingredients, quantities, containers, and reservoirs. Background light or other means for the visual inspection of products for any particulate and/or foreign matter must be used as part of the inspection process.

(B) Risk Level 2: All Risk Level 1 requirements must be met.

(C) Risk Level 3: In addition to all Risk Level 1 requirements, the process validation procedure shall be supplemented with a program of end-product sterility testing according to a formal sampling plan. Samples shall be statistically valid to ensure that batches are sterile. A method for recalling batch products shall be established if end-product testing results are unacceptable. All sterile products must be tested for sterility. All

parenteral sterile products must also be tested for pyrogenicity. Sterile products compounded from nonsterile components must be quarantined pending results of end-product testing.

1. Sterility testing: Sampling for the sterility test shall occur promptly upon the completion of preparation. The sterility test, including the sampling scheme, shall be conducted according to one (1) of the USP methods.

2. Pyrogen/Endotoxin testing: Each sterile parenteral product prepared from non-sterile drug components shall be tested for pyrogen or endotoxin according to recommended USP methods.

3. Potency: The pharmacy shall have a procedure for a pre-release check of the potency of the active ingredients in the compounded sterile product prepared from non-sterile bulk active ingredients. The procedure shall include at least the following verifications by a pharmacist:

A. The lot of the active ingredients used for compounding have the necessary labeling, potency, purity, certificate of analysis and other relevant qualities;

B. All weighings, volumetric measurements, and additions of ingredients were carried out properly;

C. The compounding or control records include documentation that the fill volumes of all units available for release were checked and were correct; and

D. The final potency is confirmed by instrumental analysis for sterile products that have been assigned a beyond-use date of more than thirty (30) days.

(D) Emergency Dispensing of a Risk Level 3 Sterile Product: When a compounded Risk Level 3 product must be released prior to the completion of testing, the sterile product may be dispensed pending test results.

#### (13) Handling Sterile Products Outside the Pharmacy.

(A) Risk Level 1: The pharmacist-in-charge shall assure the environmental control of all sterile compounded products shipped. Sterile products shall be transported so as to be protected from excesses of temperatures and light within appropriate packaging or delivery containers that maintain necessary storage conditions to preserve the quality and integrity of sterile products. The pharmacy shall follow written procedures that specify packing techniques, configuration, and materials for groups of products with common storage characteristics and for specific products where unique storage conditions are required to retain adequate stability and product quality.

(B) Risk Level 2: All requirements for Risk Level 1 must be met.

(C) Risk Level 3: All requirements for Risk Level 1 must be met.

#### (14) Cytotoxic Drugs.

(A) The following additional requirements are necessary for those licensed pharmacies that prepare cytotoxic drugs to insure the protection of the personnel involved:

1. Cytotoxic drugs shall be compounded in a vertical flow, Class II biological safety cabinet or an isolator. If used for other products, the cabinet must be thoroughly cleaned;

2. Protective apparel shall be worn by personnel compounding cytotoxic drugs which shall include disposable masks, gloves and gowns with tight cuffs;

3. Appropriate safety and containment techniques for compounding cytotoxic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile products;

4. Appropriate disposal containers for used needles, syringes, and if applicable, cytotoxic waste from the preparation of chemotherapy agents and infectious waste from patients' homes. Disposal of cytotoxic waste shall comply with all applicable local, state and federal requirements;

5. Written procedures for handling major and minor spills and generated waste of cytotoxic agents must be developed and must be included in the policy and procedure manual;

6. Prepared doses of cytotoxic drugs must be labeled with proper precautions inside and outside, and shipped in a manner to minimize the risk of accidental rupture of the primary container.

(15) Exemption: Pharmacists and pharmacies where sterile compounding is provided may be exempt from this rule when compounding is restricted to utilizing compounds or products that are contained only in a closed or sealed system and can be transferred or compounded within this self-contained system or topical products that require further transfer or combination in order to achieve a finished product without further modification of the product.

(16) In addition to the requirements outlined in this rule, all standards and requirements as outlined in 20 CSR 2220-2.400 must be maintained. Pharmacies that are registered with the Food and Drug Administration (FDA) are exempt from the distribution restrictions in 20 CSR 2220-2.400(12) for compounded sterile pharmaceuticals distributed with FDA's knowledge and enforcement discretion. This exemption applies only to a twenty-four (24)-hour course of therapy which is needed:

(A) To treat an emergency situation; or

(B) For an unanticipated procedure for which a time delay would negatively affect a patient outcome. In order to continue beyond twenty-four (24) hours, the pharmacy must obtain a prescription and comply with all record and labeling requirements as defined by law or regulation.

*AUTHORITY: sections 338.140, 338.240, and 338.280, RSMo 2000 and section 338.010, RSMo Supp. 2007.\* This rule originally filed as 4 CSR 220-2.200. Original rule filed May 4, 1992, effective Feb. 26, 1993. Amend-*

*ed: Filed Oct. 28, 1994, effective May 28, 1995. Rescinded and readopted: Filed Dec. 3, 2002, effective July 30, 2003. Moved to 20 CSR 2220-2.200, effective Aug. 28, 2006. Amended: Filed Feb. 6, 2008, effective Aug. 30, 2008.*

*\*Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007; 338.140, RSMo 1939, amended 1981, 1989, 1997; 338.240, RSMo 1951; and 338.280, RSMo 1951, amended 1971, 1981.*

## **20 CSR 2220-2.300 Record Confidentiality and Disclosure**

*PURPOSE: This rule establishes requirements for the confidentiality and disclosure of records related to patient care.*

(1) Prescription records, physician orders and other records related to any patient care or medical condition(s) of a patient that are maintained by a pharmacy in accordance with section 338.100, RSMo shall be considered confidential. Adequate security shall be maintained over such records in order to prevent any indiscriminate or unauthorized use of any written, electronic or verbal communications of confidential information.

(2) Confidential records shall not be released to anyone except—

- (A) The patient;
- (B) A health care provider involved in treatment activities of the patient;
- (C) Lawful requests from a court or grand jury;
- (D) A person authorized by a court order;
- (E) Any other person or entity authorized by a patient to receive such information;
- (F) For the transfer of medical or prescription information between pharmacists as provided by law;
- (G) Government agencies acting within the scope of their statutory authority; or
- (H) A person or entity to whom such information may be disclosed under 45 CFR Parts 160, 164 and 165 (the Privacy Standards of the Health Insurance Portability and Accountability Act of 1996).

(3) This rule does not change or otherwise alter the authority of the board, its inspectors or other authorized designees to review, inspect, copy or take possession of any such records.

(4) Methods to access, transmit, store, analyze, or purge confidential information shall be implemented using procedures generally recognized as secure by experts qualified by training and experience. Procedures shall be in place to ensure that purged confidential information cannot be misused or placed into active operation without appropriate authorization as provided in this

rule. Internet connectivity or remote access tied directly to systems containing confidential information must be secure as provided for in 4 CSR 220-2.085(2)(B).

*AUTHORITY: sections 338.100, 338.140 and 338.280, RSMo 2000.\* This rule originally filed as 4 CSR 220-2.300. Original rule filed May 4, 1995, effective Dec. 30, 1995. Rescinded and readopted: Filed Nov. 1, 2000, effective June 30, 2001. Amended: Filed Dec. 15, 2003, effective July 30, 2004. Moved to 20 CSR 2220-2.300, effective Aug. 28, 2006.*

*\*Original authority: 338.100, RSMo 1939, amended 1971, 1990, 1997, 1999; 338.140, RSMo 1939, amended 1981, 1989, 1997; 338.280, RSMo 1951, amended 1971, 1981.*

## **20 CSR 2220-2.400 Compounding Standards of Practice**

*PURPOSE: This rule defines compounding and establishes guidelines for the compounding of drugs.*

(1) Compounding is defined as the preparation, incorporation, mixing and packaging or labeling of a drug or device as the result of a prescriber's prescription or prescription drug order based on the prescriber/patient/pharmacist relationship in the course of professional practice. Compounding may also be defined as the preparation, incorporation, mixing and packaging or labeling of a drug or device, for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale or dispensing purposes.

(2) Manufacturing is defined as the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis, and includes any packaging or repackaging of the substance(s) or labeling or relabeling of its container, and the promotion and marketing of such drugs or devices.

(3) Batch compounded product is defined as a product compounded in advance of receipt of a prescription or a product compounded in a supply that will be used on more than one (1) dispensing to a patient or patients or any product compounded in excess of the filling of an individual prescription. A batch is a specific quantity of product compounded in a single, discrete process, by the same individuals, carried out during one (1) limited time period.

(4) Beyond-use date: A date after which a compounded preparation should not be used and is determined from the date the preparation is compounded. Because compounded preparations are intended for administration immediately or following short-term storage, their

beyond-use dates must be assigned based on criteria different from those applied to assigning expiration dates to manufactured drug products.

(5) Compounding Area and Equipment Requirements.

(A) The area(s) used for the compounding of drugs shall be maintained in a sanitary condition and shall be free of infestation by insects, rodents and other vermin. Trash shall be held and disposed of in a timely and sanitary manner.

(B) If drug products with special precautions for contamination, such as penicillin, are involved in a compounding operation, appropriate measures, including either the dedication of equipment for such operations or the meticulous cleaning of contaminated equipment prior to its return to inventory, must be utilized in order to prevent cross-contamination.

(C) Equipment used in the compounding of drug products shall be of appropriate design, adequate size and suitably located to facilitate operations for its intended use and for its cleaning and maintenance. Equipment used in the compounding of drug products shall be of suitable composition so that surfaces that contact ingredients, in-process materials or drug products shall not be reactive, additive or absorptive so as to alter the safety, identity, strength, quality or purity of the drug product beyond that desired.

(6) Proper controls shall be maintained over drug products/ingredients, containers and container closures.

(A) Bulk drugs and other materials used in the compounding of drugs must be stored in adequately labeled containers in a clean, dry area or, if required, under proper refrigeration.

(B) Pharmacists shall only receive, store or use drug substances for compounding that have been made and/or distributed by Missouri licensed/registered drug distributors.

(C) Pharmacists shall only use nondrug substances for compounding that are free of any contaminants and which maintain full potency.

(D) Drug products/ingredients, containers and container closures used in the compounding of drugs shall be handled and stored in a manner to prevent contamination.

(E) Drug product/ingredient containers and container closures shall not be reactive, additive or absorptive so as to alter the safety, identity, strength, quality or purity of the compounded drug beyond the desired result. Container systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded drug product.

(7) Appropriate quality control measures shall be maintained by the pharmacy and its staff over compounding methods.

(A) Such methods shall include the following and shall be followed in the execution of the drug compounding process. A separate log shall be maintained which includes:

1. Methods for the compounding of drug products to insure that the finished products have the identity, strength, quality and purity they purport or are represented to possess;

2. Date of compounding;

3. Identity of the compounding pharmacist;

4. A listing of the drug products/ingredients and their amounts by weight or volume;

5. Description of the compounding process and the order of drug product/ingredient addition, if necessary for proper compounding;

6. The identity of the source, lot number and the beyond-use date of each drug product/ingredient, as well as an in-house lot number and a beyond-use date for bulk compounded products; and

7. An identifying prescription number or a readily retrievable unique identifier for which the compound was dispensed.

(B) Information related to and the methods of compounding shall be available upon request.

(C) Pharmacists may compound drugs in limited quantities prior to receiving a valid prescription based on a history of receiving valid prescriptions that have been generated solely with an established pharmacist/patient/prescriber relationship.

1. The compounding of drug products in anticipation of receiving prescriptions without an appropriate history of such prescriptions on file or a documented need, shall be considered manufacturing instead of compounding of the drug(s) involved. Limited quantities, for purposes of this rule, are further defined as an amount of batched product that represents a three (3)-month supply.

2. Creams, ointments, lotions, liniments or other compounded products intended for external use may be batched in the same manner as provided for in paragraph (5)(C)1. of this rule that represents a one (1)-year supply.

(D) Any excess compounded products shall be stored and accounted for under conditions dictated by its composition and stability characteristics to insure its strength, quality and purity. Excess product shall be labeled with the name of the drug(s), an in-house lot number and beyond-use date.

(E) Records as outlined in this rule shall be retained and made readily retrievable for inspection for two (2) years from the date of compounding.

(F) The actual name of each active or therapeutic ingredient contained in a compound shall be listed on the container of any product provided to a consumer.

(8) Management of Compounding.

(A) A pharmacist dispensing any compounded drug is responsible for ensuring that the product has been pre-

pared, labeled, controlled, stored, dispensed and distributed properly. The pharmacist is responsible for ensuring that quality is built into the preparation of products, with key factors including at least the following general principles:

1. Personnel are capable and qualified to perform their assigned duties;

2. Ingredients used in compounding have their expected identity, quality and purity. Drug components must meet compendial standards or maintain a certificate of analysis on file when bulk drug substances are involved. Visual inspection of bulk drug substances must be performed;

3. Reasonable assurance that processes are always carried out as intended or specified;

4. Preparation conditions and procedures are adequate for preventing mix-ups or other errors; and

5. All finished products, as a condition of release, must be individually inspected for evidence of visible particulates or other foreign matter and for container-closure integrity and any other apparent visual defects.

(B) The pharmacy is responsible for developing a drug monitoring system for compounded products. The outcome monitoring system shall provide readily retrievable information suitable for the evaluation of the quality of pharmaceutical services. This shall include but not be limited to reported infection rates, incidence of adverse drug reactions, incidence of recalls and complaints from prescribers or clients.

(C) A recall must be initiated when a product is deemed to be misbranded or adulterated. The pharmacy shall notify the prescriber of the nature of the recall, the problem(s) identified and any recommended actions to ensure public health and safety.

1. In cases where the compounded product has the potential to harm the patient, the same recall notification, as provided for in this subsection, shall be provided to all patients that have received the recalled compounded product(s).

2. Any recall initiated by a pharmacy shall be reported, in writing, to the board within three (3) business days.

(9) Compounding of drug products that are commercially available in the marketplace or that are essentially copies of commercially available Federal Drug Administration (FDA) approved drug products is prohibited. There shall be sufficient documentation within the prescription record of the pharmacy of the specific medical need for a particular variation of a commercially available compound.

(10) Any alteration, change or modification to the contents of a commercially manufactured over-the-counter product shall require a prescription or prescription drug order from an authorized prescriber. The compounding of any drug product to be sold without a prescription is prohibited.

(11) Any person shown at any time, either by medical examination or pharmacist determination, to have an apparent illness or open lesion(s) that may adversely affect the safety or quality of a drug product being compounded shall be excluded from direct contact with drug products/ingredients, drug product containers, container closures and in-process materials, until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of the products being compounded.

(12) Pharmacists shall not offer compounded drug products to other pharmacies, practitioners or commercial entities for subsequent resale or administration, except in the course of professional practice for a prescriber to administer to an individual patient by prescription. A pharmacist or pharmacy may advertise or otherwise provide information concerning the provision of compounding services; however, no pharmacist or pharmacy shall attempt to solicit business by making specific claims about compounded products.

(13) In addition to the requirements outlined in this rule, all standards and requirements as outlined in 4 CSR 220-2.200 Sterile Pharmaceuticals must be adhered to whenever compounding involves the need for aseptic procedures or requires the use of or results in an intended sterile pharmaceutical product.

*AUTHORITY: sections 338.010, 338.140, 338.240 and 338.280, RSMo 2000.\* This rule originally filed as 4 CSR 220-2.400. Original rule filed Aug. 25, 1995, effective April 30, 1996. Amended: Filed Dec. 3, 2002, effective July 30, 2003. Moved to 20 CSR 2220-2.400, effective Aug. 28, 2006.*

*\*Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990; 338.140, RSMo 1939, amended 1981, 1989, 1997; 338.240, RSMo 1951; and 338.280, RSMo 1951, amended 1971, 1981.*

## **20 CSR 2220-2.450 Fingerprint Requirements**

*PURPOSE: This rule establishes guidelines for the submission of fingerprint cards for applicants for licensure.*

(1) Applicants for licensure or registration that must provide fingerprints to the Board of Pharmacy shall include:

- (A) Pharmacist examination for licensure;

- (B) Pharmacist score transfer for licensure;

- (C) Pharmacist examination for licensure by graduates of nonapproved foreign pharmacy schools;

- (D) Pharmacist licensure by reciprocity (license transfer);

- (E) Drug distributor license manager-in-charge (unless currently licensed as a pharmacist in the state of Mis-



souri);

(F) Pharmacy technician;

(G) Owners with a ten percent (10%) or more interest in a drug distributor entity (applying to non-publicly held companies only); and

(H) Intern pharmacist.

(2) Information collected under this background review will be held as confidential in accordance with state and federal laws governing the dissemination of criminal history information.

(3) Any application which is found to contain incomplete, inaccurate or false statements shall be deemed null and void. Any license or registration issued under such circumstances shall be considered a license or registration issued under the pretense of fraud, deception or misrepresentation and the board may file a complaint with the Administrative Hearing Commission to revoke or discipline the license or registration.

(4) The board may require an applicant to be fingerprinted again and pay any required fingerprinting fees, if the application process is not completed within six (6) months of the board's receipt of the application.

(5) The board may, in the course of an investigation of a licensee, require that fingerprints be submitted for a background check as provided for in this rule.

*AUTHORITY: sections 338.140 and 338.280, RSMo 2000.\* This rule originally filed as 4 CSR 220-2.450. Original rule filed Jan. 6, 1997, effective July 30, 1997. Amended: Filed April 23, 1998, effective Nov. 30, 1998. Moved to 20 CSR 2220-2.450, effective Aug. 28, 2006. Amended: Filed Aug. 21, 2006, effective April 30, 2007. Amended: Filed Feb. 6, 2008, effective Aug. 30, 2008.*

*\*Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997 and 338.280, RSMo 1951, amended 1971, 1981.*

## **20 CSR 2220-2.500 Nuclear Pharmacy—Minimum Standards for Operation**

*PURPOSE: This rule defines minimum standards for the operation of nuclear pharmacies, a specialty of pharmacy practice. This regulation is intended to supplement other regulations of the Board of Pharmacy, as well as those of other state and/or federal agencies.*

(1) Definitions.

(A) The "practice of nuclear pharmacy" means a patient-oriented service that embodies the scientific knowledge and professional judgment required to improve and promote health through the assurance of the safe and efficacious use of radiopharmaceuticals and other

drugs.

(B) The term "nuclear pharmacy" means the location where radioactive drugs, and chemicals within the classification of legend drugs, are compounded, dispensed, stored, or sold. The term "nuclear pharmacy" does not include the nuclear medicine facilities of hospitals or clinics where radiopharmaceuticals are compounded or dispensed to patients under the supervision of a licensed physician, authorized by the Nuclear Regulatory Commission and/or the Missouri Department of Health.

(C) A "qualified nuclear pharmacist" means a pharmacist who holds a current license issued by the board and who is either certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties, a pharmacist who meets minimal standards of training for status as an authorized nuclear pharmacist or an authorized user of radioactive material, as specified by the Nuclear Regulatory Commission or by agencies of states that maintain certification agreements with the Nuclear Regulatory Commission.

(D) "Radiopharmaceutical services" means the procurement, storage, handling, compounding, preparation, labeling, quality control testing, dispensing, distribution, transfer, record keeping and disposal of radiochemicals, radiopharmaceuticals and ancillary drugs, and also includes quality assurance procedures, radiological health activities, any consulting activities associated with the use of radiopharmaceuticals, health physics, and any other activities required for provision of pharmaceutical care.

(E) "Quality control testing" means the performance of appropriate chemical, biological and physical tests on compounded radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals.

(F) "Quality assurance procedures" means all activities necessary to assure the quality of the process used to provide radiopharmaceutical services, including authentication of product history and maintenance of all records as required by pertinent regulatory agencies.

(G) "Authentication of product history" means identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical or other drug.

(H) "Radiopharmaceutical" means any drug which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides. The term "radiopharmaceutical" also includes any biological product which is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

(2) General Requirements for Pharmacies Providing Radiopharmaceutical Services.

(A) No person may receive, acquire, possess, compound or dispense any radiopharmaceutical except in accordance with the provisions of this rule and the conditions of rules and regulations promulgated by the Nuclear Regulatory Commission and/or the Missouri Department of Health. The requirements of this rule are in addition to and not in substitution of, other applicable statutes and regulations administered by the State Board of Pharmacy or the Missouri Department of Health.

(B) Nothing in this rule shall be construed as requiring a licensed physician to obtain a separate license as a nuclear pharmacist, when the use of radiopharmaceuticals is limited to the diagnosis and treatment of patients under the supervision of the physician.

(C) Nothing in this rule shall be construed as requiring a licensed clinical laboratory, which is also licensed by the Nuclear Regulatory Commission and/or the Missouri Department of Health to handle radioactive materials, to obtain the services of a nuclear pharmacist, or to have a pharmacy permit, unless the laboratory is engaged in the commercial sale or resale of radiopharmaceuticals.

(D) Nothing in this rule shall be construed to require a department of nuclear medicine which is located in a hospital, which has a physician board certified in his/her specialty and which is licensed by the Nuclear Regulatory Commission and/or the Missouri Department of Health to handle radioactive materials, to obtain the services of a pharmacist or to have a nuclear pharmacy license for radiopharmaceutical preparation and distribution to patients within that institution.

(3) Permits.

(A) A permit to operate a nuclear pharmacy shall only be issued to a person who is, or who employs, a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals and ancillary drugs shall be under the direct supervision of a qualified nuclear pharmacist, who shall be in personal attendance. The pharmacist-in-charge shall be responsible for all operations of the pharmacy.

(B) The permit to operate a nuclear pharmacy is effective only so long as the pharmacy also holds a current Nuclear Regulatory Commission and/or Missouri Department of Health license. Copies of inspection reports shall be made available upon request to the board for inspection.

(C) Any nuclear pharmacy which provides (transfers) product outside of a patient specific prescription service must be licensed as a drug distributor in order to provide a product for a prescriber's use.

(4) Space, Security, Record Keeping and Equipment.

(A) Nuclear pharmacies shall have adequate space and equipment, commensurate with the scope of services

required and provided and as required by the Nuclear Regulatory Commission. All pharmacies handling radiopharmaceuticals shall include, but not be limited to, the following areas:

1. Radiopharmaceutical preparation/dispensing area;
2. Radioactive material shipping/receiving area;
3. Radioactive material storage area; and
4. Radioactive waste decay area.

(B) The nuclear pharmacy professional service area shall be secured against unauthorized personnel and must be totally enclosed and lockable.

(C) Nuclear pharmacies shall maintain records of acquisition, inventory and disposition of all radioactive drugs and other radioactive materials in accordance with State Board of Pharmacy, Nuclear Regulatory Commission and/or Missouri Department of Health statutes and regulations.

(D) Nuclear pharmacies shall compound and dispense radiopharmaceuticals in accordance with accepted standards of radiopharmaceutical quality assurance. The State Board of Pharmacy recognizes that the preparation of radiopharmaceuticals involves the compounding skills of the nuclear pharmacist to assure that the final drug product meets accepted professional standards of purity and quality.

(E) A nuclear pharmacy shall have available the following resources:

1. A vertical laminar airflow hood that is annually certified to assure aseptic conditions within the working areas;
2. A sanitary work area that is designed to avoid outside traffic and outside airflow and that is ventilated so that it does not interfere with sanitary conditions. The sanitary work area shall not be used for bulk storage of supplies or other materials;
3. A sink located nearby that is suitable for cleaning purposes;
4. A current policy and procedure manual that includes the following subjects:
  - A. Sanitation;
  - B. Storage;
  - C. Dispensing;
  - D. Labeling;
  - E. Record keeping;
  - F. Recall procedures;
  - G. Responsibilities and duties of supportive personnel;
  - H. Training and education in aseptic technique; and
  - I. Compounding procedures.

(5) Dispensing, Packaging, Labeling.

(A) A radiopharmaceutical shall be dispensed only to a licensed physician authorized by the Nuclear Regulatory Commission and/or the Missouri Department of Health to possess, use and administer such drug. A radiopharmaceutical shall be dispensed only upon receipt of a prescription or medication order from such licensed

physician. Except that a radiopharmaceutical may be transferred to a person who is authorized to possess and use the drug for nonclinical applications.

(B) Radioactive drugs are to be dispensed only upon a non-refillable prescription order from a licensed physician or the physician's designated agent. Upon receiving an oral prescription order for a radiopharmaceutical, the nuclear pharmacy shall immediately have the prescription order reduced to writing or recorded in a data processing system. The order must be taken by a pharmacist, intern pharmacist, nuclear medicine technologist or designated agents. Nuclear medicine technologists may only receive prescription orders for diagnostic radiopharmaceuticals, and all such prescriptions must be reviewed and initialed by the pharmacist. The prescription record shall contain all information as required in 4 CSR 220-2.018 Prescription Requirements and shall also include:

1. The date of dispensing and the calibration time of the radiopharmaceutical; and

2. The name of the procedure.

(C) The immediate outer container shield of a radiopharmaceutical to be dispensed shall be labeled with—

1. The name and address of the pharmacy;

2. The name of the prescriber;

3. The date of dispensing;

4. The serial number assigned to the order for the radiopharmaceutical;

5. The standard radiation symbol;

6. The words "Caution Radioactive Material";

7. The name of the procedure;

8. The radionuclide and chemical form;

9. The amount of radioactivity and the calibration date and time;

10. If a liquid, the volume;

11. If a solid, the number of items or weight;

12. If a gas, the number of ampules or vials;

13. Molybdenum-99 content to United States Pharmacopoeia (USP) limits; and

14. The patient name or the words "Physician's Use Only" in the absence of a patient name. When the prescription is for a therapeutic or blood-product pharmaceutical, the patient name shall appear on the label. The requirements of this paragraph shall be met when the name of the patient is readily retrievable from the physician upon demand.

(D) The immediate inner container label of a radiopharmaceutical to be dispensed shall be labeled with—

1. The standard radiation symbol;

2. The words "Caution Radioactive Material";

3. The identity of the radionuclide; and

4. The serial number of the radiopharmaceutical.

(E) When a radiopharmaceutical is dispensed under the authority of an Investigational New Drug Application (IND), the nuclear pharmacy records shall include an investigator's protocol for the preparation of the radiopharmaceutical, a copy of the Institutional Review Board

approval form (or letter) and a letter from the manufacturer (sponsor) indicating that the physician requesting the radiopharmaceutical is a qualified investigator.

(6) Reference Manuals.

(A) Each nuclear pharmacy shall have a copy of the Missouri Pharmacy Practice Act and current regulations under the act; one recognized text in nuclear pharmacy, and a current copy of state and federal regulations governing the safe storage, handling, use, dispensing, transport and disposal of radioactive material.

(7) Any preparation of Positron Emission Tomographic (PET) radiopharmaceuticals shall comply with 4 CSR 220-2.200 Sterile Pharmaceuticals and with applicable USP standards.

*AUTHORITY: sections 338.210, 338.240, 338.250, 338.280, 338.330(3), RSMo 1994 and 338.220 and 338.350, RSMo Supp. 1997.\* This rule originally filed as 4 CSR 220-2.500. Original rule filed Sept. 2, 1997, effective April 30, 1998. Moved to 20 CSR 2220-2.500, effective Aug. 28, 2006.*

*\*Original authority: 338.210, RSMo 1951; 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997; 338.240, RSMo 1951; 338.250, RSMo 1951, amended 1990; 338.280, RSMo 1951, amended 1971, 1981; 338.330, RSMo 1989, amended 1993; and 338.350, RSMo 1989, amended 1993, 1995.*

## **20 CSR 2220-2.600 Standards of Operation for a Class F: Renal Dialysis Pharmacy**

*PURPOSE: This rule incorporates the provisions of SB 141 and defines minimum standards for a Class F: Renal Dialysis Pharmacy.*

(1) A Class F pharmacy (renal dialysis) shall be limited in scope to the provision of dialysis products and supplies to persons with chronic kidney failure for self-administration at the person's home or specified address. Pharmacy services and dialysis supplies and products provided by a Class F pharmacy shall be limited to the distribution and delivery of drugs and devices as provided within this rule. All drugs and devices must be ordered by an authorized prescriber for administration or delivery to a person with chronic kidney failure for self-administration at the person's home or specified address. All dialysis supplies and products provided by a Class F pharmacy shall be prepackaged and shall be covered by an approved New Drug Application (NDA) or 510(k) application issued by the Food and Drug Administration (FDA).

(2) A Class F pharmacy shall maintain a pharmacist-in-charge on a consultant basis who shall review pharmacy operations at least weekly. The pharmacist-in-charge of

a Class F pharmacy will be responsible for the following requirements:

(A) Ensure that the use of legend drugs and devices that are provided to a person for the treatment of chronic kidney disease for self-administration at the person's home or specified address shall be under the professional supervision of an appropriate practitioner licensed under Missouri law.

(B) Ensure that only drugs and devices that have been ordered by an authorized prescriber and are included on the list of approved formulary drugs and devices are provided to patients;

(C) Ensure that no drugs or devices shall be dispensed to a patient until adequate training in the proper use and administration of such products has been completed;

(D) Ensure that proper documentation of drug and device distributions and deliveries are maintained by the Class F pharmacy and are made available upon request to practitioners involved in the care of the patient and to board of pharmacy representatives;

(E) Maintain a policy and procedure manual that shall be available for inspection by board of pharmacy personnel. The manual shall include a quality assurance program with which to monitor the qualifications, training and performance of personnel; and

(F) The pharmacist-in-charge shall be responsible for the drug/device delivery system and shall establish a written protocol for the implementation of the delivery system including methods for supervising drug/device deliveries to patients of the pharmacy.

1. Any written protocols shall be available for inspection by board of pharmacy personnel.

2. Any changes to the policy and procedure manual or to written protocols must be approved by the pharmacist-in-charge.

(3) Drug Formulary List/Device List. The pharmacy shall submit a list of drugs and/or devices which must be approved by the board of pharmacy.

(4) A Class F pharmacy shall deliver products to a person with chronic kidney failure only upon the receipt of a valid prescription from an authorized prescriber specifying or including:

(A) Documents that the intended recipient will require such products for the appropriate treatment of the disease and that the intended recipient has been trained in home dialysis therapy;

(B) The duration of the prescriber's order, not to exceed one (1) year, including all authorized refills; and

(C) The name and product code of each product prescribed and the quantity prescribed.

(5) Personnel of the pharmacy shall assemble the products to be delivered pursuant to the prescriber's order(s). In assembling such products for delivery, the pharmacy shall take steps necessary to assure the following:

(A) The code numbers and quantities of the products assembled match the code numbers identified in the prescriber's order(s);

(B) Any products bearing an expiration date have a minimum of three (3) full months of shelf-life remaining;

(C) A visual inspection of all drugs and devices for compliance with the prescriber's order(s) and with all labeling requirements as set forth in 338.059, RSMo. Manufacturer sealed case lots shall be labeled with the name of the patient, date, and a control number that serves as a unique patient identifier number; and

(D) Products ordered by a prescriber and provided to patients of the pharmacy shall be delivered either by personnel of the pharmacy or by a carrier authorized by the pharmacy.

1. Upon the delivery to patients of any drugs/devices, pharmacy personnel or the approved carrier shall confirm receipt by the patient or the patient's designee and that the number of units delivered equals the number of units identified by documentation supplied by the pharmacy.

(6) Class F pharmacies shall comply with all of the following:

(A) The license of the pharmacy shall be displayed in plain view at the pharmacy location;

(B) The pharmacy shall be open such hours as are necessary to safely and effectively dispense and deliver supplies to those persons designated by the applicable prescriber;

(C) The pharmacy must maintain sufficient space and storage capabilities as necessary to carry out its operations; and

(D) All drugs and/or devices shall be properly identified and any outdated, misbranded or adulterated items shall be segregated from the active inventory within a clearly separate and defined area and shall be held separately until the item is destroyed or returned to a licensed drug distributor.

*AUTHORITY: sections 338.140 and 338.220, RSMo Supp. 1997 and 338.280, RSMo 1994. \* This rule originally filed as 4 CSR 220-2.600. Original rule filed Jan. 20, 1998, effective Aug. 30, 1998. Moved to 20 CSR 220-2.600, effective Aug. 28, 2006.*

*\*Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997; 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997; and 338.280, RSMo 1951, amended 1971, 1981.*

## **20 CSR 2220-2.650 Standards of Operation for a Class J: Shared Services Pharmacy**

*PURPOSE: The purpose of this rule is to establish minimum standards of operation for Class J: Shared Services Pharmacy, in compliance with House Bill 567 of the 91st General Assembly.*

(1) Class J: Shared Services: Shared Service Pharmacy is defined as the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order, or that performs or assists in the performance of functions associated with the dispensing process, drug utilization review (DUR), claims adjudication, refill authorizations, and therapeutic interventions.

(A) A pharmacy may perform or outsource centralized prescription processing services provided the parties:

1. Have the same owner, or have a written contract outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of said contract in compliance with federal and state laws and regulations;
2. Maintain separate licenses for each location involved in providing shared services; and
3. Share a common electronic file to allow access to sufficient information necessary or required to fill or refill a prescription drug order.

(B) There must be record keeping systems between shared service pharmacies with real time on-line access to shared services by both pharmacies. Transfer of prescription information between two (2) pharmacies that are accessing the same real-time, on-line database pursuant to the operation of a shared service pharmacy operation shall not be considered a prescription transfer and, therefore, is not subject to the requirements of 4 CSR 220-2.120.

(C) The parties performing or contracting for centralized prescription processing services shall maintain a policy and procedures manual and documentation that implementation is occurring in a manner that shall be made available to the board for review upon request and that includes, but is not limited to, the following:

1. A description of how the parties will comply with federal and state laws and regulations;
2. The maintenance of appropriate records to identify the responsible pharmacist(s) in the dispensing and counseling processes;
3. The maintenance of a mechanism for tracking the prescription drug order during each step in the process;
4. The provision of adequate security to protect the confidentiality and integrity of patient information;
5. The maintenance of a quality assurance program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care and resolve identified problems.

*AUTHORITY: sections 338.140, 338.240, and 338.280, RSMo 2000 and 338.210 and 338.220, RSMo Supp. 2001.\* This rule originally filed as 4 CSR 220-2.650. Original rule filed Nov. 30, 2001, effective June 30, 2002. Amended: Filed Dec. 3, 2002, effective June 30, 2003. Moved to 20 CSR 2220-2.650, effective Aug. 28, 2006.*

*\*Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997; 338.210, RSMo 1951, amended 2001; 338.220, RSMo 1951; amended 1969, 1981, 1989, 1997, 1999, 2001; 338.240, RSMo 1951 and 338.280, RSMo 1951, amended 1971, 1981.*

## **20 CSR 2220-2.675 Standards of Operation/Licensure for Class L Veterinary Pharmacies**

*PURPOSE: This rule defines standards for a Class L veterinary pharmacy.*

(1) A Class A or a Class L pharmacy permit shall be required for any entity engaged in the sale, dispensing, or filling of a legend drug for use in animals that must only be dispensed by prescription under state or federal law. For purposes of this rule, a legend drug shall be defined as provided by 21 USC section 353.

(2) Class A Pharmacies. Class A permit holders shall comply with all laws/rules applicable to Class A pharmacies, provided a Class A pharmacy shall comply with sections (7) and (8) of this rule when legend drugs are dispensed for animal use.

(3) Class L Pharmacies. A Class L pharmacy shall dispense, sell, or provide legend drugs only for animal use. Except as otherwise provided in this rule, a Class L pharmacy shall comply with all applicable state and federal pharmacy and controlled substance laws/rules including, but not limited to, all applicable provisions of Chapter 338, RSMo, and the rules of the board.

(4) Pharmacy Operations. A Class L pharmacy shall comply with 20 CSR 2220-2.010, with the following allowed modifications:

- (A) The pharmacy permit shall be displayed in plain view at the pharmacy location;
- (B) The pharmacy shall maintain sufficient space, equipment, and storage capabilities as necessary to carry out its operations;
- (C) Legend drugs shall be properly identified and stored in a defined area within the pharmacy;
- (D) Legend drugs shall be stored in a clean and sanitary designated area and within temperature requirements as provided for by the manufacturer or the latest edition of the United States Pharmacopoeia (USP);
- (E) The pharmacy shall maintain a current reference manual related to veterinary drugs that complies with 20 CSR 2220-2.010(1)(D);

(F) Appropriate sewage disposal must be available within the pharmacy and a hot and cold water supply shall be accessible to pharmacy staff. If compounding is performed, the hot and cold water supply shall be located within the pharmacy;

(G) Pharmacy compounding shall comply with 20 CSR 2220-2.200, 20 CSR 2220-2.400, and all other applicable provisions of state/federal law;

(H) All dispensing errors shall be documented in the pharmacy's records;

(I) Animals shall not be allowed in the designated area where legend drugs are stored or maintained; and

(J) The pharmacist-in-charge shall be notified within twenty-four (24) hours after a dispensing error is learned by pharmacy staff. Documentation of notification shall be maintained in the pharmacy's prescription records.

(5) A Class L pharmacy shall designate a pharmacist-in-charge as required by 20 CSR 2220-2.010(1)(M). The pharmacist-in-charge shall be responsible for supervising pharmacy operations and ensuring compliance with the provisions of this rule and all applicable state/federal laws. Except as otherwise provided in this rule, the pharmacist-in-charge shall also—

(A) Ensure legend drugs are only sold, dispensed, or filled by the pharmacy for animal use;

(B) Ensure legend drugs have been ordered/prescribed by an authorized prescriber; and

(C) Maintain a policy and procedure manual for pharmacy operations. The policy and procedure manual shall be reviewed annually by the pharmacist-in-charge. The manual shall be available for inspection by board personnel and shall include policies and procedures for:

1. Accepting, compounding, dispensing, or filling prescriptions;

2. Accepting, dispensing, or filling prescriptions in the pharmacist's absence;

3. Drug storage and security;

4. Handling drug recalls;

5. Procedures for offering patient/client counseling;

6. If applicable, procedures for dispensing or providing prescriptions in a pharmacist's absence pursuant to section (8) of this rule;

7. Contacting the pharmacist-in-charge for consultation during the pharmacy's business operations or in the event of an emergency; and

8. Reporting and handling dispensing errors. The pharmacist-in-charge shall be notified of a dispensing error within twenty-four (24) hours after the error is learned by pharmacy staff. Policies/procedures shall include the manner of notification.

(6) A pharmacist shall not be required to be physically present on-site during the business operations of a Class L pharmacy if the pharmacist-in-charge reviews the activities and records of the pharmacy operations on a monthly basis to ensure compliance with this rule.

This exemption shall not apply if the pharmacy sells, dispenses, or otherwise provides controlled substances. The date of the pharmacist-in-charge review shall be documented and maintained at the pharmacy.

(7) To be valid for purposes of dispensing, legend drug prescriptions for animal use shall conform to all requirements of sections 338.056 and 338.196, RSMo, and shall contain the following:

(A) The date issued;

(B) The client's/owner's name and the class, species, or identification of the animal, herd, flock, pen, lot, or other group being treated;

(C) The prescriber's name, if an oral prescription, or signature, if a written prescription;

(D) Name, strength, and dosage form of drug and directions for use;

(E) The number of refills, when applicable;

(F) The quantity prescribed in weight, volume, or number of units;

(G) The address of the prescriber and the patient when the prescription is for a controlled substance;

(H) Whether generic substitution has been authorized;

(I) The prescriber's Drug Enforcement Administration (DEA) number when the prescription is for a controlled substance; and

(J) Controlled substance prescriptions shall comply with all requirements of federal and state controlled substance laws.

(8) Dispensing. A Class L pharmacy may accept, fill, enter, dispense, or otherwise provide non-controlled legend drugs for animal use in the absence of a pharmacist, provided the pharmacist-in-charge shall review the prescription record for each such prescription on a monthly basis. The review shall be documented as provided in section (6) of this rule. For purposes of 20 CSR 2220-2.010(3), the dispensing pharmacist shall be identified as the pharmacist-in-charge unless dispensed by another licensed pharmacist.

(A) Legend drugs may only be compounded for use in animals when a pharmacist is present on site.

(B) Clients must be offered an opportunity to consult with a pharmacist as required by 20 CSR 2220-2.190. If the pharmacist is not present on site, a written offer to counsel with a contact telephone number for a pharmacist shall be supplied with the medication.

(9) Labeling. Prescriptions must be labeled as required by section 338.059, RSMo. Prescription labels may be manually written and numbered and shall include:

(A) The class, species, or identification of the animal, herd, flock, pen, lot, or other group being treated; and

(B) If applicable, the veterinarian's specified withdrawal, withholding, or discard time for meat, milk, eggs, or any other food which might be derived from the treated animal(s).

(10) Records. Class L pharmacy records shall be maintained as required by Chapter 338, RSMo, and the rules of the board, including, 20 CSR 2220-2.018 and 20 CSR 2220-2.080.

(A) The information specified in section (7) of this rule shall be required and recorded on all handwritten, telephone, oral, and electronically produced prescriptions that are processed for dispensing by a pharmacist/pharmacy. If applicable, prescription records shall also include the veterinarian's specified withdrawal, withholding, or discard time identified in section (9) of this rule.

(B) Any change or alteration made to the prescription dispensed based on contact with the prescriber shall be documented in the pharmacy's prescription records. This shall include, but is not limited to, a change in quantity, directions, number of refills, or authority to substitute a drug.

(C) The pharmacy's prescription records shall identify any prescription dispensed in a pharmacist's absence pursuant to section (8) of this rule.

(11) A Class L pharmacy shall comply with all applicable state or federal controlled substance laws.

(12) The provisions of this rule shall not be applicable to the sale of medication for use in animals that may lawfully be dispensed without a prescription nor shall this rule be construed to require licensure for entities solely engaged in selling, dispensing, or providing medications authorized for dispensing without a prescription.

(13) The provisions of this rule shall not prohibit or interfere with any legally registered practitioner of veterinary medicine in the compounding, administering, prescribing, or dispensing of their own prescriptions, medicine, drug, or pharmaceutical product to be used for animals.

**AUTHORITY:** sections 338.056, 338.059, 338.196, 338.250, 338.280, and 338.343, RSMo 2000, and sections 338.010, 338.055, 338.140, 338.150, 338.210, 338.220, and 338.240, RSMo Supp. 2011.\* *Emergency rule filed Aug. 29, 2011, effective Sept. 8, 2011, expired March 5, 2012. Original rule filed Aug. 29, 2011, effective March 30, 2012.*

*\*Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011; 338.055, RSMo 1971, amended 1978, 1981, 1986, 1998, 2001, 2004, 2011; 338.056, RSMo 1978, amended 1996; 338.059, RSMo 1971, amended 1973, 1978, 1997; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; 338.150, RSMo 1939, amended 1951, 1961, 1980, 1981, 2011; 338.196, RSMo 1991; 338.210, RSMo 1951, amended 2001, 2011; 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997, 1999, 2001, 2004, 2007, 2011; 338.240, RSMo 1951, amended 2011; 338.250, RSMo 1951, amended 1990, 1998; 338.280, RSMo 1951, amended 1971, 1981; and 338.343, RSMo 1989, amended 1993.*

## **20 CSR 2220-2.700 Pharmacy Technician Registration**

**PURPOSE:** *This rule defines the requirements for pharmacy technician registration.*

(1) A pharmacy technician is defined as any person who assumes a supportive role under the direct supervision and responsibility of a pharmacist and who is utilized according to written standards of the employer or the pharmacist-in-charge to perform routine functions that do not require the use of professional judgement in connection with the receiving, preparing, compounding, distribution, or dispensing of medications.

(A) No person shall assume the role of a pharmacy technician without first registering with the board in accordance with the requirements in section 338.013, RSMo and this rule. Nothing in this rule shall preclude the use of persons as pharmacy technicians on a temporary basis as long as the individual(s) is registered as or has applied to the board for registration as a technician in accordance with 338.013.1 and .2, RSMo.

(B) A person may be employed as a technician once a completed application and the required fee is received by the board. The board will provide either a registration certificate that shall be conspicuously displayed or a letter of disqualification preventing the applicant's employment within a pharmacy.

(C) Information required on the application shall include, but is not limited to—

1. The name, phone number, and residential address of the applicant;

2. Full-time and part-time addresses where the applicant will be employed as a technician;

3. Information concerning the applicant's compliance with state and federal laws, as well as any violations that could be considered grounds for discipline as outlined in section 338.013.5, RSMo;

4. One (1) two-inch by two-inch (2" × 2") frontal view portrait photograph of applicant; and

5. Proof of fingerprinting as required by 20 CSR 2220-2.450.

(D) A copy of the application must be maintained by the applicant at the site(s) of employment during and until notice of registration or disqualification is received by the applicant and must be readily retrievable for review by the board of pharmacy or the board's representatives.

(2) Registered technicians as well as applicants for registration as a technician are responsible for informing the board in the case of a changed residential address. Any mail or communications returned to the board office marked unknown, incorrect address, and the like will not be mailed a second time until the correct address is provided.

(3) Registered technicians as well as applicants for registration as a technician shall inform the executive director of the board of any change in their employment ad-

dress. The notification of an employment change must be provided in writing to the board no later than fifteen (15) days following the effective date of the change.

(4) Any person whose name appears on the board of pharmacy employment disqualification list shall be barred from employment as a pharmacy technician except as provided in section (5) of this rule.

(A) Information on the disqualification list shall include, at a minimum, the name and last known residential address of the person disqualified, as well as any previous registration number, the date on which the person's name was entered on the list and the date at which time the person will again become eligible for employment in a pharmacy. The board may place a person on the disqualification list for an indefinite period of time if the disqualified person fails to maintain a current mailing address with the board or fails to communicate with the board on a timely basis when contacted in writing by the board.

(B) Once the board has made a determination to place a person's name on the disqualification list, the board shall notify the person in writing by mailing the notification to the person's last known address. The disqualification notice shall include:

1. The name, address of residence and, if already registered as a technician, the registration number;
2. The reasons for being placed on the disqualification list;
3. The consequences of the person's name appearing on the list;
4. The time period of disqualification;
5. Any alternative restrictions or provisions for conditional employment, if provided by the board; and
6. The right to appeal the decision of the board as provided in Chapter 621, RSMo.

(5) Any person whose name appears on the disqualification list may be employed as a pharmacy technician subject to any restrictions or conditions ordered by the board. As an alternative to barring an individual from employment in a pharmacy, the board may consider restricted forms of employment or employment under special conditions for any person who has applied for or holds a registration as a pharmacy technician. Special conditions may include participation in the board's Well-Being Program, as provided in 20 CSR 2220-2.175. Any registered technician subject to restrictions or conditions who violates any portion of the restrictions or conditions may be further restricted in employment or have additional conditions placed on their registration. The board may also implement full disqualification on a registrant who has violated any restrictions or conditions.

(6) The letter of notice of intent to disqualify and the disqualification list shall be considered an open record of the board as well as any notice of appeal or litigation that pertains to the disqualification and/or conditional registration as a pharmacy technician.

*AUTHORITY: sections 338.013 and 338.380, RSMo Supp. 2009, and section 338.140, RSMo 2000.\* This rule originally filed as 4 CSR 220-2.700. Original rule filed Aug. 21, 1998, effective Feb. 28, 1999. Amended: Filed Nov. 13, 2002, effective June 30, 2003. Moved to 20 CSR 2220-2.700, effective Aug. 28, 2006. Amended: Filed Aug. 18, 2009, effective March 30, 2010.*

*\*Original authority: 338.013, RSMo 1997, 2004, 2009; 338.140, RSMo 1939, amended 1981, 1989, 1997; and 338.380, RSMo 2007.*

## **20 CSR 2220-2.800 Vacuum Tube Drug Delivery System**

*PURPOSE: This rule defines the minimum standards for a vacuum tube drug delivery system utilized in licensed pharmacies.*

(1) Vacuum tube systems are for use in the delivery of drugs to the patient or his/her agent.

(A) Any drug delivery system that utilizes a vacuum tube to deliver drugs outside of a licensed pharmacy must be designed and engineered in such a way as to ensure security of all drugs and that drugs are delivered correctly and efficiently to the intended recipient.

(B) Only systems that are dedicated for the delivery of drugs from a location within a licensed pharmacy to another location specific for drug delivery and are not connected, combined or attached to other systems shall be used. Multiple or switchable stations where the delivery of drugs could occur at more than one destination outside of the pharmacy are prohibited.

1. When the pharmacy is closed or there is no pharmacist on duty, the vacuum tube system must be turned off and no drugs shall be delivered to consumers during these time periods.

(C) Any pharmacy, which cannot maintain a direct and identifiable line of sight with the consumer, must maintain a video camera and audio system to provide for effective communication between pharmacy personnel and consumers. It must be a system that will allow for the appropriate exchange of oral as well as written communications to facilitate patient counseling and other matters involved in the correct transaction or provision of drugs.

1. Video monitors used for the proper identification of persons receiving prescription drugs shall be a minimum of twelve inches (12") wide.

2. Both the video monitor and the audio system must be in good working order or operations utilizing the vacuum tube system shall cease until appropriate corrections or repairs are made to the system(s).

3. Backlighting or other factors that may inhibit video or audio performance must be taken into account when using such systems to identify recipients of prescription drugs. Positive identification of recipients must be made before any drug is delivered.

(2) All vacuum tube delivery systems installed after Sep-



tember 1, 1998, shall comply with the minimum standards set forth in this rule. Any vacuum tube delivery system already installed in a pharmacy prior to September 1, 1998, will not be required to comply with this rule; except that, should the vacuum tube delivery system or any part thereof require replacement, change, or upgrading after September 1, 1998, the system or any part of the system being replaced, changed or upgraded shall comply with the minimum standards set forth in this rule. This exemption does not relieve a pharmacy of its duty to maintain adequate security measures as required by 4 CSR 220-2.010(1)(H); nor does it relieve pharmacists from their duty to provide patient counseling as required by 4 CSR 220-2.190.

*AUTHORITY: sections 338.140, RSMo Supp. 1997 and 338.280, RSMo 1994.\* This rule originally filed as 4 CSR 220-2.800. Original rule filed Aug. 21, 1998, effective Feb. 28, 1999. Moved to 20 CSR 2220-2.800, effective Aug. 28, 2006.*

*\*Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997 and 338.280, RSMo 1951, amended 1971, 1981.*

## **20 CSR 2220-2.900 Automated Dispensing and Storage Systems**

*PURPOSE: This rule establishes guidelines for the use of automated dispensing and storage systems.*

(1) Automated dispensing and storage systems (hereafter referred to as automated system or system) are hereby defined to include, but are not limited to, mechanical systems that perform operations or activities, relative to the storage, packaging or dispensing of medications, and which collect, control, and maintain all transaction information. Such systems may be used in pharmacies and

where a pharmacy permit exists, for maintaining patient care unit medication inventories or for a patient profile dispensing system, provided the utilization of such devices is under the supervision of a pharmacist. A pharmacist is not required to be physically present at the site of the automated pharmacy system if the system is supervised electronically by a pharmacist. In order to supervise the system within an ambulatory care setting, the pharmacist must maintain constant visual and auditory communication with the site and full control of the automated system must be maintained by the pharmacist and shall not be delegated to any other person or entity. Supervision of an automated refill patient self-service device requires that a pharmacist employed by the pharmacy by which the device is owned and operated be available at all times during operating hours of the pharmacy.

(A) Documentation shall be maintained by the owner/operator of an automated system for the type of equipment, locations where all systems are located, identification of all persons accessing the automated system,

the identity of persons stocking or restocking the system and the pharmacist responsible for checking the accuracy of medications stocked.

(B) Automated systems that are used within licensed health care facilities shall be used only in settings that ensure medication orders are reviewed by a pharmacist in accordance with established policies and procedures and laws governing the practice of pharmacy. A pharmacist shall control all operations of the automated system and approve the release of the initial dose of a prescription drug order. Subsequent doses from an approved prescription drug order may be removed from the automated system after this initial approval. Any change made in the prescription drug order shall require a new approval by a pharmacist to release the drug.

(C) In ambulatory care settings, a pharmacist must input all information from a prescription or prescription drug order into the electronic data system utilized for the initiation of the dispensing of a drug at a remote site and maintain proper oversight over the entire dispensing process. A pharmacist shall be accessible at all times to respond to patient's or other health professionals' inquiries or requests pertaining to drugs dispensed through the use of the automated pharmacy system. No prescription shall be prepared or dispensed from a remote automated system unless it is from a prescriber providing clinical services at the same location. Labeling of drug containers must be in accordance with section 338.059, RSMo, and application of labels to containers must occur prior to release of the prepared prescription drug from the automated system. Labels shall contain both the name, address and phone number of the supervising pharmacy and the remote dispensing site.

(D) When automated systems are located at remote sites the central pharmacy responsible for the operation and supervision of a remote site must maintain separate and readily retrievable records of all transactions and prescriptions processed by each remote automated system. Remote automated sites must provide the name, address and toll free telephone number of the supervising pharmacy displayed on the automated dispensing system in a prominent location.

(E) Automated systems shall maintain adequate security systems and procedures to prevent unauthorized access or use and shall at all times maintain compliance with all state and federal drug laws including all controlled substance requirements and patient confidentiality laws.

1. Any remote automated system that stocks controlled substances must maintain a perpetual inventory from each site.

2. Automated systems in ambulatory care settings must be located in an area that will provide adequate space for private consultations to occur and must only be installed within the same area utilized by the prescriber for the provision of clinical services.

3. Automated refill patient self-service devices must be physically attached to the pharmacy so that access to areas used to restock the device are only accessible through the pharmacy physical plant by pharmacy per-

sonnel.

(F) Restocking of automated systems shall be done by registered technicians under the supervision of a pharmacist or by a pharmacist.

(G) All events involving access to the contents of the automated system must be recorded electronically.

(H) No medication or device shall be returned directly to the system for reissue or reuse by a person not licensed or registered by the board of pharmacy.

(I) Quality assurance documentation for the use and performance of the automated systems shall be maintained for a minimum period of two (2) years and shall include at a minimum the following:

1. Breach of security of the automated system;
2. Failure of the system to operate correctly along with the frequency of any failures and the necessary repairs completed;
3. Tests completed to measure the effectiveness and accuracy of the system. every six (6) months and whenever any upgrade or change is made to the system.

(J) Drugs that are repackaged for use in automated systems at remote locations must comply with 20 CSR 2220-2.130 Drug Repackaging requirements. Automated refill patient self-service devices must comply with all labeling and dispensing laws governing the provision of medication refills to patients. Products that are considered temperature sensitive or products that require further manipulation in order to be ready for use by a patient shall not be provided through patient self-service devices, unless the device has the capability to provide storage conditions in compliance with Food and Drug Administration (FDA) requirements.

(K) If an automated system uses removable cartridges or containers to hold drugs, the prepackaging of the cartridges or containers must occur at the pharmacy where the original inventory is maintained unless provided by a FDA approved repackager and who is licensed as a drug distributor. The prepackaged cartridges or containers may be sent to the automated system at remote locations to be loaded into the machine by registered technicians under the supervision of a pharmacist or by a pharmacist provided that—

1. A pharmacist has verified the container has been properly filled and labeled;
2. The individual containers are transported to the automated system in a secure, tamper-evident container; and
3. The automated system utilizes technologies to ensure that the containers are accurately loaded in the automated system.

(L) Any pharmacy that maintains an automated system for remote dispensing to ambulatory patients must maintain a video camera and audio system to provide for effective communication between pharmacy personnel and consumers. It must be a system that will allow for the appropriate exchange of oral as well as written communications to facilitate patient counseling as provided in 20 CSR 2220-2.190 and other matters involved in the correct transaction or provision of drugs.

1. Video monitors used for the proper identification

and communication with persons receiving prescription drugs shall be a minimum of twelve inches (12") wide and provided at both the pharmacy and remote location for direct visual contact between pharmacist and patient.

2. Both the video monitor and the audio system must be in good working order or operations utilizing the automated system shall cease until appropriate corrections or repairs are made to the system(s).

3. Backlighting or other factors that may inhibit video or audio performance must be taken into account when using such systems to identify recipients of prescription drugs. Positive identification of recipients must be made before any drug is delivered.

(2) Each automated system shall maintain a manual of policies and procedures that, at a minimum, shall include the following:

(A) System operations that include specific and measurable accountability for safety, security, accuracy, patient confidentiality, access, data retention and retrieval, downtime procedures, emergency first dose or refill patient self-service procedures, inspection of systems by pharmacy personnel, installation requirements, maintenance, medication security, quality assurance, inventory levels and control, staff education and training and system set-up and malfunction.

(B) Documentation by the automated system at remote locations for on-site patient administration and remote dispensing of medications that includes specific identification of patients, medications used along with dates and times the system is utilized.

(C) Effective procedures for securing and accounting for wasted medications or discarded medications.

(D) Access to and limits on access (security levels) to the automated system must be defined and must comply with applicable state and federal laws and regulations.

(3) The pharmacist-in-charge is responsible for the overall compliance of the automated system in the same manner as other pharmacy operations as outlined in 4 CSR 220-2.090. In addition, responsibilities will also include:

(A) Establishment of a quality assurance program prior to implementation of an automated system and the supervision of an ongoing quality assurance program that monitors appropriate use and performance of the automated system, which is evidenced by written policies and procedures developed by the pharmacy;

(B) Assign, discontinue or change access to the automated system;

(C) Assure that the automated system is in good working order and accurately provides the correct strength, dosage form and quantity of a drug prescribed while maintaining appropriate record keeping and security safeguards.

(D) Procedures used for notifying the board on a timely basis and other state and federal agencies, when warranted, of any breach of security which results in the unauthorized removal of drugs.

(4) Except where otherwise noted in this rule, all records specified must be retained as a part of the dispensing record of the pharmacy and in accordance with section 338.100, RSMo and board regulations governing the proper maintenance and retrieval of records.

(5) Pharmacies that maintain automated sites for dispensing drugs to ambulatory patients shall maintain a Class J: Shared Service classification on each pharmacy permit involved in such activity.

(6) The supervising pharmacy shall have sufficient pharmacists on duty such that each pharmacist may supervise no more than three (3) remote sites that are simultaneously open to provide services. An exception to the supervision limit may be granted by the board in situations where the provider has documented a need for a pharmacist to supervise additional remote sites and has demonstrated that appropriate safeguards are in place to assure proper supervision of each remote site.

*AUTHORITY: sections 338.210 and 338.220, RSMo Supp. 2006 and 338.140 and 338.280, RSMo 2000.\* This rule originally filed as 4 CSR 220-2.900. Original rule filed Nov. 1, 2000, effective June 30, 2001. Amended: Filed Feb. 18, 2003, effective Sept. 30, 2003. Moved to 20 CSR 2220-2.900, effective Aug. 28, 2006. Amended: Filed Aug. 21, 2006, effective April 30, 2007.*

*\*Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997; 338.210, RSMo 1951, amended 2001; 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997, 1999, 2001, 2004; and 338.280, RSMo 1951, amended 1971, 1981.*



20 CSR 2220-3



**Title 20—DEPARTMENT OF  
INSURANCE, FINANCIAL  
INSTITUTIONS AND  
PROFESSIONAL REGISTRATION  
Division 2220—State Board of Pharmacy  
Chapter 3—Negative Generic  
Drug Formulary**

**20 CSR 2220-3.010 Generic Drug Formulary**

This rule originally filed as 4 CSR 220-3.010. Emergency rule filed Dec. 28, 1978, effective Jan. 7, 1979, expired April 30, 1979. Moved to 20 CSR 2220-3.010, effective Aug. 28, 2006.

**20 CSR 2220-3.011 Generic Drug Formulary**

*PURPOSE: The purpose of this rule is to comply with the section 338.057, RSMo (1986), which directs the Department of Economic Development to publish a list of drug products for which substitution, by a pharmacist shall not be permitted. Noting that there are a number of drug products within a specific drug product category that have been proven bioequivalent and bio-available to the Federal Food and Drug Administration, the Department of Economic Development has delineated within a particular drug product category those drugs that may be substituted. The list is dual in nature. There are certain drugs where substitution will not be permitted and there are certain drug products where qualified substitution will be allowed, again only if the drug and manufacturer is specifically designated in the list.*

**PUBLISHER'S NOTE:** The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. Therefore, the material which is so incorporated is on file with the agency who filed this rule, and with the Office of the Secretary of State. Any interested person may view this material at either agency's headquarters or the same will be made available at the Office of the Secretary of State at a cost not to exceed actual cost of copy reproduction. The entire text of the rule is printed here. This note refers only to the incorporated by reference material.

(1) If a written prescription is involved, the prescription form used shall have two (2) signature lines at opposite ends at the bottom of the form. Under the line at the right side shall be clearly printed the words: "Dispense as Written." Under the line at the left side shall be clearly printed the words "Substitution Permitted." The prescriber shall communicate the instructions to the pharmacist by signing the appropriate line. No prescription shall be valid without the signature of the prescriber on one (1)

of these lines.

(2) All pharmacists and dispensing physicians should be warned that any drug product not holding an approved New Drug Application or Abbreviated New Drug Application may not be used as a substitute in the state of Missouri without the dispenser assuming some personal liability.

(3) A pharmacist shall not substitute drug products that are rated as therapeutically inequivalent to other pharmaceutically equivalent products as listed in the latest edition or cumulative supplement of The Approved Drug Products with Therapeutic Equivalence Evaluations published by the United States Government, Department of Health and Human Services.

(4) Any drug that is manufactured by an innovator company under a supplement to their New Drug Application (NDA) for that specific drug may apply to the Missouri Board of Pharmacy for consideration as a drug that is generically equivalent to the innovator product. A written request for such consideration must be accompanied by an affidavit or other acceptable documentation from the Food and Drug Administration (FDA) attesting to the equivalency of the generic product to the innovator product. Once the Missouri Board of Pharmacy determines that the two (2) products are considered generically equivalent under state law, an appropriate notation will be made in the next revision of the Generic Drug Formulary.

*AUTHORITY: sections 338.056, 338.057 and 338.140, RSMo 1994.\* This rule originally filed as 4 CSR 220-3.011. Emergency rule filed April 26, 1979, effective May 6, 1979, expired Aug. 12, 1979. Original rule filed April 26, 1979, effective Aug. 13, 1979. Emergency amendment filed April 14, 1982, effective April 24, 1982, expired Aug. 22, 1982. Amended: Filed April 14, 1982, effective July 11, 1982. Emergency amendment filed June 14, 1982, effective July 15, 1982, expired Oct. 12, 1982. Amended: Filed June 14, 1982, effective Sept. 11, 1982. Emergency amendment filed Dec. 6, 1982, effective Jan. 1, 1983, expired March 10, 1983. Amended: Filed Dec. 6, 1982, effective March 11, 1983. Emergency amendment filed June 14, 1983, effective July 15, 1983, expired Sept. 15, 1983. Amended: Filed June 14, 1983, effective Sept. 11, 1983. Emergency amendment filed Dec. 12, 1983, effective Jan. 1, 1984, expired March 14, 1984. Amended: Filed Dec. 12, 1983, effective May 11, 1984. Emergency amendment filed Feb. 3, 1984, effective Feb. 13, 1984, expired June 12, 1984. Emergency amendment filed June 20, 1984, effective June 30, 1984, expired Oct. 28, 1984. Amended: Filed July 9, 1984, effective Oct. 11, 1984. Emergency amendment filed Dec. 10, 1984, effective Dec. 20, 1984, expired April 19, 1985. Amended: Filed Dec. 11, 1984,*

effective March 11, 1985. Emergency amendment filed Jan. 18, 1985, effective Jan. 28, 1985, expired May 28, 1985. Emergency amendment filed June 14, 1985, effective June 24, 1985, expired Oct. 12, 1985. Amended: Filed June 14, 1985, effective Sept. 27, 1985. Emergency amendment filed Dec. 23, 1985, effective Jan. 2, 1986, expired June 2, 1986. Amended: Filed Dec. 23, 1985, effective May 11, 1986. Emergency amendment filed June 21, 1986, effective July 1, 1986, expired Oct. 28, 1986. Amended: Filed June 23, 1986, effective Sept. 26, 1986. Emergency amendment filed Dec. 10, 1986, effective Dec. 20, 1986, expired April 19, 1987. Amended: Filed Dec. 10, 1986, effective April 11, 1987. Emergency amendment filed July 5, 1987, effective July 20, 1987, expired Nov. 17, 1987. Amended: Filed July 7, 1987, effective Oct. 25, 1987. Emergency amendment filed Jan. 19, 1988, effective Feb. 1, 1988, expired May 30, 1988. Amended: Filed Jan. 19, 1988, effective April 28, 1988. Amended: Filed April 15, 1988, effective Jan. 1, 1989. Emergency amendment filed July 5, 1988, effective July 15, 1988, expired Nov. 12, 1988. Amended: Filed July 5, 1988, effective Nov. 11, 1988. Emergency amendment filed Jan. 19, 1989, effective Feb. 10, 1989, expired May 19, 1989. Amended: Filed Jan. 19, 1989, effective May 11, 1989. Amended: Filed March 31, 1989, effective Sept. 1, 1989. Amended: Filed Aug. 25, 1995, effective April 30, 1996. Moved to 20 CSR 2220-3.011, effective Aug. 28, 2006.

*\*Original authority: 338.056, RSMo 1978; 338.057, RSMo 1978; and 338.140, RSMo 1939, amended 1981, 1989.*

## **20 CSR 2220-3.040 Return and Reuse of Drugs and Devices**

**PURPOSE:** *This rule sets guidelines for the return and reuse of drugs and devices.*

(1) Pharmacists and pharmacies shall not accept from patients or their agents for reuse or resale any drugs, prescribed medications, chemicals, poisons or medical devices unless otherwise provided for in this regulation.

(2) A pharmacist or pharmacy may receive and reuse drugs from long-term care facilities, hospitals, and hospice facilities (as regulated by the Department of Health and Senior Services, in 19 CSR 30-35.020 Hospices Providing Direct Care in a Hospice Facility), provided that the following conditions are met:

(A) The pharmacist has assurance from a person in responsible charge of the drugs at a facility delineated in this section that the drugs being returned have been stored in accordance with the manufacturer's recommendations and meet U.S.P. standards;

(B) The drugs were originally dispensed by the pharmacist or pharmacy to the facility delineated in section (2);

(C) There is an established mechanism to trace the expiration date and the manufacturer's lot number of the drugs being returned;

(D) Only drug products dispensed by a licensed pharmacy utilizing one (1) of the following sources may be reused and no drug products for reuse shall be in any way subject to further repackaging:

1. Drug products in the original manufacturer's packaging that remains sealed in tamper-evident packaging;

2. Drug products repackaged by facilities that are federally registered as a repackager of medications and the packaging remains sealed in tamper-evident packaging;

3. Drug products that have been repackaged by a licensed pharmacy and are returned unused by the facility and remain sealed in tamper-evident packaging;

4. Drug products that have been repackaged by a licensed pharmacy and are provided in unit of use packaging whereby unused portions can be separated and reused without any further repackaging processes necessary on the returned product; and

(E) Any products that are accepted for return and can be reused based on standards provided in this rule shall be re-labeled to provide accurate information concerning patient and prescription information. Original lot numbers, expiration or beyond-use-dates assigned to a product that is reused by a pharmacy shall not be altered or in any way updated.

(3) Pharmacists and pharmacies may return to stock prescriptions that have not been received by the patient and shall delete the dispensing from the pharmacy's records and reverse the claim with the third party payor, if applicable. In order for a product to be returned to stock, it must have been stored at all times at the manufacturer's labeled storage requirements. The drug must be maintained in the patient container with the dispensing date, prescription number, and name of drug visible. The expiration date of the drug shall become the lesser of one (1) year from the dispensing date on the label or the manufacturer's original expiration date, if known.

**AUTHORITY:** *section 338.280, RSMo 2000.\* This rule originally filed as 4 CSR 220-3.040. Original rule filed Dec. 12, 1983, effective May 11, 1984. Amended: Filed July 5, 1988, effective Nov. 11, 1988. Amended: Filed Sept. 2, 1997, effective April 30, 1998. Amended: Filed April 5, 2002, effective Nov. 30, 2002. Amended: Filed May 17, 2004, effective Dec. 30, 2004. Moved to 20 CSR 2220-3.040, effective Aug. 28, 2006. Amended: Filed Feb. 6, 2008, effective Aug. 30, 2008.*

*\*Original authority: 338.280, RSMo 1951, amended 1971, 1981.*



20 CSR 2220-4



**Title 20—DEPARTMENT OF  
INSURANCE, FINANCIAL  
INSTITUTIONS AND  
PROFESSIONAL REGISTRATION  
Division 2220—State Board of Pharmacy  
Chapter 4—Fees Charged by the Board of Pharmacy**

**20 CSR 2220-4.010 General Fees**

*PURPOSE: This rule establishes and fixes the various fees and charges authorized by Chapter 338, RSMo.*

(1) The following fees are established by the State Board of Pharmacy:

(A) Licensure by Examination Fee .....	\$ 150
1. Exam candidate shall contact the National Association of Boards of Pharmacy and pay any fee required directly by that agency.	
(B) Licensure By Transfer of License (Reciprocity).....	\$ 375
(C) Original Pharmacy Permit Fee.....	\$ 300
(D) Pharmacist License Renewal Fee.....	\$ 200
(E) Pharmacy Permit Renewal Fee.....	\$ 450
(F) Delinquent Pharmacist Renewal Fee (in addition to the Pharmacist License Renewal Fee).....	\$ 250
(G) Duplicate License/Permit/ Registration Fee.....	\$ 20
(H) Change of Pharmacy or Drug Distributor Name Fee.....	\$ 25
(I) Fee for Retake of Multistate Pharmacy Jurisprudence Examination (MPJE).....	\$ 150
(J) Foreign Graduate Preliminary Filing Fee (Candidates for licensure by examination, who are graduates of schools/ colleges of pharmacy not accredited by the board).....	\$ 250
(K) Change of Pharmacy or Drug Distributor Location Fee.....	\$ 175
(L) Original Pharmacy Distributor/ Wholesale Drug Distributor License Fee (includes both temporary and permanent license).....	\$ 300
(M) Pharmacy Distributor/ Wholesale Drug Distributor License Renewal Fee.....	\$ 450
(N) Original Drug Distributor (Manufacturer) Registration	

Filing Fee.....	\$ 10
(O) Renewal of Drug Distributor (Manufacturer) Registration Filing Fee.....	\$ 10
(P) Original Intern Pharmacist License.....	\$ 50
(Q) Intern Pharmacist License Renewal.....	\$ 80
(R) Temporary Pharmacist License Fee (original issue/renewal).....	\$ 100
(S) Fingerprint Fee for Criminal Background Check— Determined by Federal Bureau of Investigation (FBI) and Missouri State Highway Patrol (MSHP) (pass through fee)	
(T) Pharmacy Technician Initial Registration Fee.....	\$ 35
(U) Pharmacy Technician Annual Renewal Fee.....	\$ 35
(V) Delinquent Continuing Education Pharmacist Fee.....	\$1000
(W) Score Transfer Fee.....	\$ 150
(X) Pharmacy Classification Change Fee.....	\$ 50
(Y) Manager-in-Charge Change Fee.....	\$ 50
(Z) Pharmacist-in-Charge Change Fee.....	\$ 50
(AA) Verification Fee.....	\$ 25
(BB) Returned Check Fee.....	\$ 25
(CC) Certification of Medication Therapeutic Plan Authority.....	\$ 50

(2) All fees are nonrefundable.

(3) The provisions of this rule are declared severable. If any fee fixed by this rule is held invalid by a court of competent jurisdiction or by the Administrative Hearing Commission, the remaining provisions of this rule shall remain in full force and effect, unless otherwise determined by a court of competent jurisdiction or by the Administrative Hearing Commission.

*AUTHORITY: sections 338.020, 338.040, 338.060, 338.070, 338.185, 338.280, and 338.350, RSMo 2000, and sections 338.035, 338.140, 338.220, and 338.335, RSMo Supp. 2012.\* This rule originally filed as 4 CSR 220-4.010. Emergency rule filed July 15, 1981, effective Aug. 3, 1981, expired Nov. 11, 1981. Original rule filed Aug. 10, 1981, effective Nov. 12, 1981. Emergency amendment filed March 8, 1982, effective April 1, 1982, expired July 10, 1982. Amended: Filed March 8, 1982, effective June 11, 1982. Amended: Filed May 6, 1983, effective Aug. 15, 1983. Amended: Filed Dec. 11, 1984, effective March 11, 1985. Amended: Filed June 14, 1985, effective Aug. 26, 1985. Amended: Filed Aug. 27, 1985, effective Nov. 11, 1985. Amended: Filed Oct. 11, 1985, effective Dec. 26, 1985. Amended: Filed Dec. 16, 1985, effective May 11, 1986. Amended: Filed May 4,*

1987, effective Aug. 28, 1987. Amended: Filed Jan. 19, 1988, effective April 28, 1988. Amended: Filed June 2, 1988, effective Aug. 25, 1988. Amended: Filed Dec. 10, 1990, effective June 10, 1991. Amended: Filed Feb. 4, 1991, effective June 10, 1991. Amended: Filed Aug. 4, 1992, effective April 8, 1993. Amended: Filed May 24, 1993, effective Dec. 9, 1993. Amended: Filed Oct. 17, 1994, effective May 28, 1995. Amended: Filed May 3, 1996, effective Dec. 30, 1996. Amended: Filed Jan. 6, 1997, effective July 30, 1997. Amended: Filed April 23, 1998, effective Nov. 30, 1998. Amended: Filed March 15, 2000, effective Sept. 30, 2000. Amended: Filed March 1, 2001, effective Sept. 30, 2001. Amended: Filed May 17, 2004, effective Dec. 30, 2004. Amended: Filed June 15, 2005, effective Jan. 30, 2006. Moved to 20 CSR 2220-4.010, effective Aug. 28, 2006. Amended: Filed Feb. 14, 2008, effective Aug. 30, 2008. Emergency amendment filed July 6, 2012, effective July 31, 2012, expired Feb. 28, 2013. Amended: Filed July 6, 2012, effective Jan. 30, 2013.

20 CSR 2220-5



**Title 20—DEPARTMENT OF  
INSURANCE, FINANCIAL  
INSTITUTIONS AND  
PROFESSIONAL REGISTRATION  
Division 2220—State Board of Pharmacy  
Chapter 5—Drug Distributor**

**20 CSR 2220-5.010 Drug Distributor Advisory Committee**

*PURPOSE: This rule establishes operating guidelines for the drug distributor advisory committee.*

(1) As authorized in section 338.140.4., RSMo, an advisory committee, composed of five (5) members, one (1) of whom shall be a representative of pharmacy, but who shall not be a member of the pharmacy board, three (3) of whom shall be representatives of wholesale drug distributors, as defined in section 338.330, RSMo, and one (1) of whom shall be a representative of drug manufacturers, shall be appointed by the State Board of Pharmacy.

(2) Appointments to the advisory committee shall be made by the president of the board.

(A) Except for the initial committee appointments, each appointment shall be for a term of five (5) years. Beginning with the first committee appointments, the terms will be staggered so that one (1) term will expire each year after that.

(B) No appointment shall become effective until approved by the board. Each candidate shall meet with the board prior to any decision by the board to confirm. This meeting will be held in order for the board to review the candidate's credentials and to familiarize him/her with board personnel and advisory committee responsibilities.

(C) Terms of new committee members shall commence on July 1, unless the appointment is to fill an unexpired term.

(3) The advisory committee shall organize by the election of a chairman and vice-chairman who shall hold their offices for one (1) year and until their successors shall have been elected and qualified. A majority of the committee shall constitute a quorum for the transaction of business.

(4) The advisory committee shall review and make any recommendations to the board on the merit of all rules dealing with pharmacy distributors, wholesale drug distributors and drug manufacturers which are proposed by the board.

(A) The advisory committee shall maintain minutes of all meetings held.

(B) Any recommendations made by the advisory committee concerning proposed regulations shall be noted

and explained in the minutes which will be provided to the board at an open session meeting of the board. The advisory committee may provide other documentation, reports or correspondence to the board when necessary.

(C) Any official recommendations to be made from the committee to the board must be initiated by a motion that receives a majority vote in favor by the committee. This motion and vote shall be recorded in the minutes.

(D) The board will review any recommendations made by the advisory committee and will provide a response to the committee if any action is taken or modifications are made to a proposed regulation. In addition, the board shall note in the Missouri Register the dates and a summary of any recommendations made by the advisory committee on a proposed rule and report any responses that are made to those recommendations from the board.

(5) Committee members shall be reimbursed for all reasonable and necessary expenses for attending committee meetings. However, only expenses incurred within Missouri will routinely be reimbursed. No request for the compensation of expenses provided in this rule shall be processed for payment unless sufficient funds are available for that purpose within the appropriation of the State Board of Pharmacy.

*AUTHORITY: section 338.390, RSMo Supp. 1989.\* This rule originally filed as 4 CSR 220-5.010. Original rule filed Jan. 3, 1990, effective April 26, 1990. Moved to 20 CSR 2220-5.010, effective Aug. 28, 2006.*

*\*Original authority: 338.390, RSMo 1989.*

**20 CSR 2220-5.020 Drug Distributor Licensing Requirements**

*PURPOSE: This rule defines terms and requirements for the lawful licensure of drug distributors.*

(1) A "wholesale drug distributor" is defined in section 338.330(3), RSMo. No wholesale drug distributor with physical facilities located in the state of Missouri shall knowingly purchase or receive legend drugs and/or drug related devices from a wholesale drug distributor or pharmacy not licensed or registered by the board. Knowledge of the licensure status of a drug distributor or pharmacy includes, but is not limited to, actual or constructive knowledge. Knowledge of the license status of a drug distributor or pharmacy shall also include, but not be limited to, notification from the board by mail or electronic transmission.

(A) A wholesale drug distributor is further defined as anyone engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufac-

turers' and distributors' warehouses, chain drug warehouses and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.

(B) A wholesale drug distributor does not include:

1. The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug for emergency medical reasons. For purposes of this section, emergency medical reasons includes transfers of prescription drugs by a licensed pharmacy to anyone other than a licensed pharmacy that constitutes five percent (5%) or less of total gross sales of the pharmacy; and

2. The sale, purchase or trade of blood and blood components intended for transfusion and any other exemptions as provided for in Chapter 338, RSMo.

(C) Wholesale drug distributors shall inform the board of their current FAX number, any change in FAX number, and/or the fact that the wholesale drug distributor does not have a working FAX. In the event a wholesale drug distributor notifies the board that the wholesale drug distributor does not have a working FAX, notification from the board will be made to the wholesale drug distributor by first class mail. For the purposes of this rule, such notification by mail shall be considered effective three (3) days after mailing and shall have the same effect as notification by FAX.

(D) Failure to receive notification from the board shall not be a defense to violations of section (1) of this rule when the wholesale drug distributor has failed to comply with the requirements of subsection (1)(C) of this rule.

(2) All licenses for the operation of a drug distributor shall expire on the date specified by the director of the Division of Professional Registration by appropriate rule.

(3) Drug distributor licenses shall be issued on the application of the owners. If the owner is a corporation, an officer of the corporation must sign the application as the applicant. If the owner is a partnership, a partner must sign the application as the applicant. If the owner is a limited liability partnership, a general partner must sign the application as the applicant. If the owner is a limited liability company, a member must sign the application as the applicant.

(4) Drug distributor license applications and renewal applications shall be completed and submitted to the Board of Pharmacy along with the appropriate fees before any license is issued or renewed. Information required on the application shall include:

(A) The name, full business address, electronic facsimile transmission number (FAX) and telephone number of the licensee;

(B) All trade or business names used by the licensee;

(C) The address, telephone number and the name of the manager in charge for each facility used by the licensee for the storage, handling and distribution of pre-

scription drugs;

(D) The type of ownership or operation;

(E) The name(s) of the owner, operator, or both, of the licensed entity, including:

1. If a person, the name of the person;

2. If a partnership, the name of each partner and the name of the partnership;

3. If a corporation, the name of the corporate president, vice president, secretary, treasurer, chief executive officer, board of directors, and senior vice presidents or their equivalents, the corporate name(s) and the name of the state of incorporation; and

4. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity;

(F) The name of the manager-in-charge who meets the requirements as set forth in 20 CSR 2220-5.030(2); a complete notarized manager-in-charge affidavit of the license application; and a history of employment/occupations and offices held during the past seven (7) years; and

(G) An application for a wholesale or pharmacy drug distributor license will become null and void if the applicant fails to complete the process for licensure within six (6) months of receipt of the application by the board.

(5) When a drug distributor changes ownership, the original license becomes void on the effective date of the change of ownership. Before any new business entity resulting from that change opens a facility as a drug distributor, it must obtain a new license from the board. A temporary license shall be issued once a completed application and fee have been received by the board. The effective date of the temporary license shall be the date the change of ownership is listed as effective on the application. Such license shall remain in effect until a permanent license is issued or denied by the board.

(A) A change of ownership of a drug distributor facility owned by a sole proprietor is deemed to have occurred when—

1. The business is sold and the sale becomes final;

2. The proprietor enters into a partnership with another individual or business entity; or

3. The proprietor dies; provided, however, that the proprietor's estate may continue to operate the drug distributor facility for a period of no more than one (1) year and only so long as appropriate fees are paid.

(B) If a corporation owns a drug distributor facility, it is not necessary to obtain a new license if the owners of the stock change. If a limited liability partnership or a limited liability company owns a drug distributor company, it is not necessary to obtain a new license if the partners or members of the company change, as long as the partnership or company is not dissolved by that change. It is necessary to file written notice with the Board of Pharmacy within thirty (30) days after a change occurs of twenty-five percent (25%) or more in the ownership of corporation stock, or in partners in a limited liability



partnership, or in members of the limited liability company. This notification must be in writing and certified. However, when a corporation, limited liability partnership, or limited liability company begins ownership of a drug distributor company or ceases ownership of a drug distributor company, a new license must be obtained regardless of the relationship between the previous and subsequent owners.

(6) If an individual or business entity operating a drug distributor facility changes the location of the facility either within the existing facility (structure) or to a new facility (structure), the facility shall not open for business at the new location until the board, its duly authorized agent or the Food and Drug Administration has inspected the premises of the new location and approved it and the facility has been in compliance with all state and federal drug laws pertaining to drug distribution. Upon this approval and receipt of a change of location fee, the board shall issue a license authorizing operation of a facility at the new location and the license shall bear the same number as the previous license. However, the license remains valid if the facility address changes, but not the location, and an amended license will be issued without charge under these circumstances.

(7) Separate licenses shall be required for each drug distribution site owned or operated by a drug distributor as defined in section 338.330, RSMo.

(8) The Board of Pharmacy may grant a temporary license to a wholesale or pharmacy drug distributor to allow for the conduct of business within the state until a determination by the board is made on the issuance of a permanent license.

(A) Temporary licenses shall remain valid until a time the board shall find that the applicant meets or fails to meet the requirements for regular licensure or one (1) year, whichever is less.

1. The board will consider, at a minimum, the following factors in reviewing the qualifications of persons who apply or renew as a drug distributor:

A. Any convictions of the applicant under any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

B. The person has been finally adjudicated and found guilty, or entered a plea of guilty or nolo contendere, in a criminal prosecution under the laws of any state or of the United States, for any offense reasonably related to the qualifications, functions or duties of any profession licensed or regulated under this chapter, for any offense an essential element of which is fraud, dishonesty or an act of violence, or for any offense involving moral turpitude, whether or not sentence is imposed;

C. The applicant's past experience in the manufacture or distribution of prescription drugs, including con-

trolled substances;

D. The applicant furnishing false or fraudulent material in any application made in connection with drug manufacturing or distribution;

E. Suspension, revocation or probation by federal, state or local government of any license or registration currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

F. Compliance with licensing requirements under previously granted licenses, if any; and

G. Requirements to maintain or make available, or both, to the board or the federal, state or local law enforcement officials those records required under this section are followed.

2. If an applicant for a license in any way fails to provide information as requested by the board or does not cooperate with requests and inquiries made by the board or provides false or misleading information to the board and the temporary license expires or is denied, all fees paid by the applicant shall be forfeited.

3. During the period of time that a temporary license is in effect, the applicant may conduct business in this state as a drug distributor as long as all state and federal laws governing drug distribution are followed and no action that results in professional misconduct as outlined in section 338.055, RSMo is documented.

4. If it is determined by the board that a permanent license is to be denied to an applicant, a denial notification letter shall be sent to the applicant. The temporary license will be considered invalid ten (10) days after notification is sent to the applicant by certified mail.

(B) A license must be posted in a conspicuous place in the facility to which it is issued.

(9) Each licensed corporate wholesale distributor located outside of this state that distributes drugs in this state shall designate a registered agent in this state for service of process. Any licensed corporate wholesale distributor that does not designate a registered agent shall be deemed to have designated the secretary of state of this state to be its true and lawful attorney, upon who may be served all legal process in any action or proceeding against any licensed corporate wholesale distributor growing out of or arising from such distribution. Service of process shall be accomplished as authorized by law.

*AUTHORITY: sections 338.330, 338.333, 338.335, 338.337, 338.340 and 338.350, RSMo 2000.\* This rule originally filed as 4 CSR 220-5.020. Original rule filed Feb. 4, 1991, effective June 10, 1991. Amended: Filed April 28, 1992, effective Feb. 26, 1993. Amended: Filed Jan. 27, 1995, effective Sept. 30, 1995. Amended: Filed March 15, 2000, effective Sept. 30, 2000. Amended: Filed Nov. 1, 2000, effective June 30, 2001. Amended: Filed April 6, 2001, effective Nov. 30, 2001. Amended: Filed June 16, 2003, effective Jan. 30, 2004. Amended:*

*Filed June 15, 2005, effective Jan. 30, 2006. Moved to 20 CSR 2220-5.020, effective Aug. 28, 2006. Amended: Filed Aug. 21, 2006, effective April 30, 2007.*

*\*Original authority: 338.330, RSMo 1989, amended 1993, 1998; 338.333, RSMo 1989; 338.335, RSMo 1998; 338.337, RSMo 1989; 338.340, RSMo 1989; and 338.350, RSMo 1989, amended 1993, 1995.*

## **20 CSR 2220-5.025 Termination of Business as a Drug Distributor**

*PURPOSE: This establishes guidelines for the termination of business as a drug distributor.*

(1) A licensed drug distributor who plans to terminate business activities shall file a written notice with the State Board of Pharmacy. The written notice shall be submitted to the State Board of Pharmacy in person or by registered or certified mail within (15) days after the date of termination. This notice shall be made on a form provided by the board or in letter form from the licensee and shall include the following information:

(A) The name, address, license number and effective date of closure;

(B) The name, address and license number of the entity to which any of the stock/inventory will be transferred; and

(C) The name and address of the location to which records, required to be maintained by law, have been transferred;

1. Any records that are transferred to an unlicensed location must be retrievable for board review within seven (7) working days of a request made by an authorized official of the board;

2. Any records that are transferred to a licensed drug distributor or pharmacy must be maintained in accordance with record requirements as set forth in 4 CSR 220-5.030.

(2) The licensee terminating business may transfer all drugs and records in accordance with the following:

(A) On the date of termination, a complete inventory of all controlled substances being transferred or disposed of shall be completed according to state and federal laws. This inventory shall serve as the final inventory of the drug distributor terminating business and as the initial inventory of the licensed entity to which the controlled substances are being transferred. A copy of the inventory shall be included in the records of each licensee involved in the transfer;

(B) A drug distributor terminating business shall not transfer misbranded, outdated or adulterated drugs, except for purposes of proper disposal; and

(C) Upon the actual termination of business, the license of the drug distributor shall be returned to the State Board of Pharmacy for cancellation either in person or

by registered or certified mail.

(3) The requirements of this rule are not intended to replace or be in conflict with any other laws or regulations governing the appropriate licensure, change of ownership or change of location of a drug distributor.

(4) The termination date is the date on which the drug distributor licensee ceases to do business as a distributor as defined in section 338.330(1), (2) or (3), RSMo in the state of Missouri.

*AUTHORITY: sections 338.333 and 338.350, RSMo 1994.\* This rule originally filed as 4 CSR 220-5.025. Original rule filed May 4, 1995, effective Dec. 30, 1995. Moved to 20 CSR 2220-5.025, effective Aug. 28, 2006.*

*\*Original authority: 338.333, RSMo 1989 and 338.350, RSMo 1989, amended 1993.*

## **20 CSR 2220-5.030 Definitions and Standards for Drug Wholesale and Pharmacy Distributors**

*PURPOSE: This rule provides standards for the proper storage, maintenance, labeling and distribution of drugs by drug wholesale and pharmacy distributors, and further defines methods of inspections and quality assurance used by the Board of Pharmacy to ensure the public's safety in these areas. For purposes of this rule, the term drug distributor will be used to define all entities that are licensed under section 338.330, RSMo and are subject to this rule.*

(1) Drug distributors must maintain standards of practice that will ensure that only drugs of appropriate quality will be distributed to practitioners for further compounding and dispensing to the public. These standards shall be subject to periodic reviews through the board's inspection process.

(A) This process will include on-site inspections for drug distributors who are located in this state and may include border states or by requesting information on licensure and inspections conducted by other states or the federal government through the board office.

(B) For purposes of this rule, the term drug distributor, when used, defines anyone engaged in any activity as defined in section 338.330, RSMo.

(2) No drug distributor license will be issued unless the facility is under the direct supervision of a manager-in-charge.

(A) The board shall consider the same factors in reviewing the qualifications of someone who is appointed as a manager-in-charge as those outlined in 20 CSR 2220-5.020(8)(A)1.

(B) A person must also have appropriate education, experience, or both, before assuming the duties of man-

ager-in-charge. Appropriate education for purposes of this section is defined as education in the areas of work environment, standards of operation and knowledge of laws concerning drug distributor compliance and requirements.

1. Minimum requirements for education/experience may be attained separately or in combination to total two (2) years.

2. Experience within a drug wholesale or pharmacy distributor facility or in any education endeavor beyond a certificate of graduation from an accredited high school or its equivalent may be utilized in meeting these minimum requirements.

(C) Any individual that is considered a manager or supervisor within a facility but is not the manager-in-charge of the facility must meet the minimum education/experience requirements as set forth in this rule for a total of one (1) year.

(D) The licensee shall require all other persons employed in any prescription drug wholesale distribution activity to have education, training and experience, or any combination, sufficient for that person to perform the assigned functions in a manner as to provide assurance that the drug product quality, safety and security at all times will be maintained as required by law.

(E) Drug distributor operations must be conducted at all times under the supervision of a properly designated manager-in-charge. The manager-in-charge must be actively involved and aware of the actual daily operations of the drug distributor operation. The manager-in-charge must be physically present at the drug distributor operation during normal business hours, except for time periods when absent due to illness, scheduled vacation or other authorized absence; and be aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the drug distributor operation. When the person who is manager-in-charge resigns or is terminated from the position, the holder of the license shall immediately notify the board office of the resignation or termination of the manager-in-charge and by notarized affidavit give the name of the new manager-in-charge.

(3) Minimum standards of practice for drug distributors shall include the following:

(A) The facility must be of a suitable size and construction to facilitate cleaning, maintenance and proper operations;

(B) The temperature of the facility where drugs are stored must be maintained thermostatically within temperature requirements as provided for by the manufacturer or the latest edition of the United States Pharmacopeia (USP). Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, logs, or all of these, shall be utilized to document proper storage of prescription drugs;

(C) Appropriate housekeeping, sanitation, lighting, ventilation and humidity of all areas where drugs are stored

must be maintained.

1. All aisles and walkways must be free and clear of debris, dirt or filth.

2. Dust shall be kept at low levels through adequate ventilation, cleaning procedures, or both.

3. All shelves and storage areas shall be kept free of debris, dirt, dust and filth.

4. Full cases of drug products shall be raised above floor level and placed on a pallet or similar device.

5. Upon receipt of legend drugs, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

6. Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

7. Drugs stored in a facility or being processed for distribution must be physically separated at all times from articles, supplies or other drugs that are outdated, distressed, misbranded or adulterated. An area separate from drug storage must be used to store quarantined, nonusable substances or accumulated waste/garbage. Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier. If a drug is received or further distributed, either directly or through a secondary broker (paper) transaction, that is wholly or in part found to be counterfeit, a report which includes the name of the drug, quantity and lot number(s) must be forwarded to the Board of Pharmacy within seven (7) days of gaining knowledge of the transaction. Any recall of a product that is initiated by the Food and Drug Administration (FDA) or by a vendor licensed with the state of Missouri shall not be subject to the reporting requirement.

8. Flammable articles must be stored separately and away from drug products held for later wholesale distribution.

9. Drugs which may be held for later distribution that are labeled for veterinary use must be stored separately from those drugs that are to be distributed for human use.

10. Procedures must be in place to prevent, control and alleviate infestation by insects, rodents, birds or vermin of any kind. Animals, except for service animals as defined by the Americans with Disabilities Act (ADA), are not allowed in the drug storage areas.

11. Appropriate sewage disposal and a hot and cold water supply must be available.

12. The outside perimeter of the premises shall be

well-lighted.

13. All facilities shall be equipped with an alarm system to detect entry after hours.

14. All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records;

(D) The drug distributor license issued to the facility must be displayed in a public area;

(E) Adequate refrigeration must be available to ensure enough storage space for drugs requiring refrigeration or freezing and under temperatures adequate to maintain the drug products as recommended by the manufacturer, the latest edition of the USP, or both;

(F) The labeling of drug products held for wholesale distribution must conform to requirements as set forth by the manufacturer, FDA, the USP and section 338.059.2, RSMo;

(G) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, then the drug shall be destroyed or returned to the supplier, unless examination, testing or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the drug distributor shall consider, among other things, the conditions under which the drug has been held, stored or shipped before or during its return and the condition of the drug and its container, carton or labeling, as a result of storage or shipping;

(H) Drugs held for wholesale distribution must be stored in a secure area where only authorized personnel have access to them. Sufficient locking mechanisms must be in place and a list of personnel who possess keys or passes which allow them to have independent access to any part of a facility which stores drugs held for later distribution or where any controlled substances are stored must be maintained. Records on all past employees who have had access to drug storage or processing areas must be maintained for a period of three (3) years;

(I) Wholesale drug and pharmacy distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include the following information:

1. The source of the drugs, including the name and principal address of the seller or transferor and the address of the location from which the drugs were shipped;

2. The identity and quantity of the drugs received and distributed or disposed of; and

3. The dates of receipt and distribution or other disposition of the drugs;

(J) Inventories and records shall be made available

for inspection and photocopying by authorized federal, state or local law enforcement agency officials for a period of three (3) years following disposition of the drugs;

(K) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by the board or its representatives;

(L) Record requirements as described in this rule shall be followed for appropriate accountability and disposition for all outdated, damaged, deteriorated, misbranded or adulterated prescription drugs;

(M) Wholesale drug and pharmacy distributors shall establish, maintain and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Drug distributors shall include in their written policies and procedures the following:

1. A procedure where the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement if the deviation is temporary and appropriate;

2. A procedure to be followed for handling recalls and withdrawals of prescription drugs. This procedure shall be adequate to deal with recalls and withdrawals due to any—

- A. Action initiated at the request of the FDA or other federal, state, or local law enforcement or other government agency, including the Board of Pharmacy;

- B. Voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

- C. Action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design;

3. A procedure to ensure that drug distributors prepare for, protect against and handle any crisis that affects the security or operation of any facility in the event of strike, fire, flood or other natural disaster, or other situations of local, state or national emergency;

4. A procedure for reporting counterfeit or suspected counterfeit drugs or devices or counterfeiting or suspected counterfeiting activities to the board;

5. A procedure for the mandatory reporting to the board and any other appropriate federal or state agency of all shortages of prescription drugs and devices where it is known or suspected that diversion or theft is occurring;

6. A procedure for investigating discrepancies involving counterfeit, suspect of being counterfeit, contraband, or suspect of being contraband in the inventory and reporting such discrepancies within seven (7) business

days to the board and any other appropriate federal or state agency shall be maintained by each drug distributor;

7. A procedure for reporting criminal or suspected criminal activities involving the inventory of drug(s) and device(s) to the board within the seven (7) business days; and

8. A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for three (3) years after disposition of the outdated drugs.

(N) Drug distributors will be responsible for security procedures for the delivery of drugs from the wholesale facility to the destination site of all drug shipments; and

(O) No drug distributor license shall be issued to any location, regardless of zoning, that is a residence or that shares an address and/or physical space with a business not related to the distribution of prescription drugs or drug-related devices, or not licensed and regulated by the state of Missouri.

(4) In addition to standards listed in this rule for drug distributors, drug repackagers must observe federal standards for—

- (A) Packaging;
- (B) Record keeping;
- (C) Expiration dating;
- (D) Plant facilities;
- (E) Equipment;
- (F) Personnel;
- (G) Production and control procedures;
- (H) Containers;
- (I) Testing; and
- (J) Federal registration requirements.

(5) Agents or employees of licensed or registered drug distributors may have legend drugs in their custody if they are acting in the usual course of business or employment and their names and addresses and the addresses of all sites where drugs are stored have been provided to the board.

(A) Storage and transport of drugs by agents or employees of drug distributors must be maintained in accordance with manufacturer or USP guidelines and must be free of contamination, deterioration or adulteration.

(B) Drug distributors shall report to the board any agents or employees that are registered pursuant to this section of this rule for any convictions for violations of state or federal drug laws.

(6) Drug distributors shall establish and maintain lists of officers, directors, managers and other persons in charge of wholesale drug distribution, storage and handling, including a description of their duties and a sum-

mary of their qualifications.

(7) Drug distributors shall be subject to the provisions of any applicable federal, state or local laws or regulations that relate to prescription drug product salvaging or reprocessing, including Parts 207, 210 and 211 of the Federal Food, Drug and Cosmetic Act.

(8) The executive director of the board, at his/her discretion, may grant exemptions to compliance with portions of section (3) of this rule when such exemptions are not contrary to federal drug distributor laws and the exemption is limited to a specific request. Any exemption requests by a licensed drug distributor must be submitted in writing. Any exemptions that are granted as outlined in this section will be provided in writing.

(9) As used in section 338.330(3), RSMo, the term “drug related device” shall be defined as an article that is not considered a prescription drug under federal law, but which meets the definition of a device as provided in 21 U.S.C. 321(h) and 21 U.S.C. 360j(e).

*AUTHORITY: sections 338.333, 338.343 and 338.350, RSMo 2000.\* This rule originally filed as 4 CSR 220-5.030. Original rule filed Feb. 4, 1991, effective June 10, 1991. Amended: Filed Jan. 27, 1995, effective Sept. 30, 1995. Amended: Filed March 15, 2000, effective Sept. 30, 2000. Amended: Filed Nov. 1, 2000, effective June 30, 2001. Amended: Filed May 13, 2005, effective Oct. 30, 2005. Moved to 20 CSR 2220-5.030, effective Aug. 28, 2006. Amended: Filed Aug. 21, 2006, effective April 30, 2007. Amended: Filed Feb. 6, 2008, effective Aug. 30, 2008.*

*\*Original authority: 338.333, RSMo 1989; 338.343, RSMo 1989, amended 1993; and 338.350, RSMo 1989, amended 1993, 1995.*

## **20 CSR 2220-5.040 Drug Distributor Inspection Exemptions**

*PURPOSE: This rule defines requirements for Board of Pharmacy inspection exemption of wholesale drug and pharmacy distributors.*

(1) Inspections of drug distribution facilities shall be conducted by the board in accordance with the provisions as outlined in section 338.360, RSMo. Any drug distributor facility which has been inspected by the Food and Drug Administration (FDA) over a period of less than two (2) years and can demonstrate that all inspections resulted in a satisfactory rating shall be exempt from further inspection by the board until and upon the time that any inspection of the premises of the facility results in a less than satisfactory rating or the last full inspection by the FDA is two (2) years old or greater.

(A) For purposes of this rule, the results of federal inspections that are deemed to be less than satisfactory shall include, but not be limited to, any documentation as to deficiencies in any drug distribution, repackaging, labeling, quality control or environmental policies or procedures, or both. Deficiencies may be defined as any statement which is a part of a compliance report recorded by federal inspection with or without sanctions, penalties, fines or discipline imposed.

1. For purposes of further definition, an inspection that is conducted by the FDA that is used for exemption purposes must be a full inspection of all operations and procedures of the facility. Abbreviated inspectional options as defined in federal policy guidelines may not be considered to fulfill the exemption requirements as provided in section 338.360, RSMo and this rule.

2. Any drug distribution facility which has been granted an exemption from inspection must notify the board at any time of an inspection conducted by the FDA or the Drug Enforcement Administration that results in less than a satisfactory rating as defined in subsection (1)(A) of this rule.

*AUTHORITY: section 338.350, RSMo Supp. 1989. \* This rule originally filed as 4 CSR 220-5.040. Original rule filed Feb. 4, 1991, effective June 10, 1991. Moved to 20 CSR 2220-5.040, effective Aug. 28, 2006.*

*\*Original authority: 338.350, RSMo 1989.*

## **20 CSR 2220-5.050 Out-of-State Distributor License/Registration Requirements**

*PURPOSE: This rule establishes guidelines for license/registration procedures for out-of-state drug distributors.*

(1) Out-of-state wholesale drug distributors or out-of-state pharmacy distributors may be licensed, as required by sections 338.210—338.370, RSMo, by reciprocity if they—

(A) Possess a valid license in good standing in the state or foreign jurisdiction in which they are located pursuant to legal standards comparable to those which must be met by a distributor of this state as prerequisites for obtaining a license under the laws of this state; and

(B) Are located in a state or foreign jurisdiction which extends reciprocal treatment under its own laws to a wholesale distributor of this state.

(2) Out-of-state wholesale drug and pharmacy distributors shall not ship, mail or deliver prescription drugs into Missouri without first obtaining a license from the Missouri Board of Pharmacy.

(A) In order for an out-of-state wholesale drug or pharmacy distributor to maintain a license, it must comply with each of the following:

1. Maintain in good standing a license from the state

or foreign jurisdiction in which the nonresident distributor is located provided that a license is issued by that state or foreign jurisdiction;

2. Submit an application as provided by the board for licensure in compliance with sections 338.333 and 338.337, RSMo and with 4 CSR 220-5.020;

3. Pay all appropriate fees;

4. Submit a copy of the state or foreign jurisdiction license or its equivalent from the state or foreign jurisdiction in which the distributor is located provided that a license is issued by that state or foreign jurisdiction;

5. Submit a copy of the state or foreign jurisdiction and federal controlled substance registrations from the state or foreign jurisdiction in which they are located, if controlled substances are to be shipped into Missouri; and

6. Submit copies, when requested by the board, of any inspection reports, warning notices, notice of deficiency reports or any other related reports from the state or foreign jurisdiction in which it is located concerning the operation of an out-of-state drug or pharmacy distributor for review of compliance with state, federal or foreign jurisdiction drug laws.

(B) The Missouri Board of Pharmacy will extend reciprocal cooperation to any state or foreign jurisdiction that licenses and regulates out-of-state drug or pharmacy distributors for the purpose of investigating complaints against distributors located in Missouri or the sharing of information and investigative reports, as long as the other state or foreign jurisdiction will extend the same reciprocal cooperation to the Missouri Board of Pharmacy.

(3) An exemption to licensure is allowed when an out-of-state wholesale drug distributor supplies a drug to another drug distributor licensed in this state in an emergency situation. The amount of the distribution allowed must be confined to the emergency situation and the total amount of distribution for emergency situations must not exceed one percent (1%) of the total annual gross sales of the unlicensed distribution site.

(4) Registration in lieu of licensure may be sought by an out-of-state drug distributor when the following provisions exist:

(A) The out-of-state drug distributor is a drug manufacturer;

(B) The manufacturing facility is used for both the production (manufacture) and distribution of legend drugs;

(C) The site has been inspected with a satisfactory rating by the Food and Drug Administration within the last two (2) years. Inspections of these facilities must comply with all standards and requirements as outlined in 4 CSR 220-5.040;

(D) The state in which the manufacturing facility is located issues a license and the license is current and in good standing; and

(E) The out-of-state distributor who qualifies for registration must complete an application as provided by the

board and submit it along with a filing fee of ten dollars (\$10).

1. The board shall provide, on an annual basis, a registration renewal form to all registered out-of-state distributors.

2. In order for a registration to remain in good standing and in effect, the renewal must be returned to the Division of Professional Registration by an expiration date that is specified by the director of the division by appropriate rule.

3. In order for a registration to be renewed, it must comply with all the provisions for registering as a drug distributor facility as outlined in section 338.337, RSMo and this rule.

4. Each renewal application must be submitted along with a filing fee of ten dollars (\$10).

*AUTHORITY: sections 338.330, 338.335 and 338.350, RSMo Supp. 1999 and 338.333 and 338.337, RSMo 1994.\* This rule originally filed as 4 CSR 220-5.050. Original rule filed Feb. 4, 1991, effective June 10, 1991. Amended: Filed March 15, 2000, effective Sept. 30, 2000. Moved to 20 CSR 2220-5.050, effective Aug. 28, 2006.*

*\*Original authority: 338.330, RSMo 1989, amended 1993, 1998; 338.333, RSMo 1989; 338.335, RSMo 1998; 338.337, RSMo 1989; 338.350, RSMo 1989, amended 1993, 1995.*

## **20 CSR 2220-5.060 Controlled Substance Reporting**

*PURPOSE: This rule defines requirements for reporting the distribution of controlled substances from drug and pharmacy distributors to persons and facilities that are registered with the Federal Drug Enforcement Administration.*

(1) Wholesale drug and pharmacy distributors that distribute Schedule II products and Schedule III narcotics Automation of Reports and Consolidated Orders (ARCOS products) shall provide a listing of those products distributed within the state to the board on a quarterly basis when requested to do so by the board. In addition, wholesale drug and pharmacy distributors that distribute controlled substances within the state shall provide up to a twenty-four (24) month retrospective listing of all controlled substances (Schedule II through Schedule IV) distributed within the state or to a specific location to the board when requested to do so by the board. The board shall submit the request thirty (30) days in advance of the information requested. Reports must be submitted to the board either on hard copy in typewritten form or by electronic media. If electronic media is used in providing the reports, it shall be provided in one (1) of the following formats.

(A) If an electronic tape is used, it shall be an IBM

9-track, labeled or nonlabeled, 1600 or 6250 bits per inch (bpi);

(B) If a diskette is used, it shall be either a MacIntosh 400K or 800K; MS-DOS 5 1/4" 360K or 1.2 meg; MS-DOS 3 1/2" 720K or 1.44 meg; or an IBM 8" diskette; or

(C) If a cartridge is used, it shall be a 1/2" tape, 3480 Compatible.

*AUTHORITY: section 338.350, RSMo Supp. 1989.\* This rule originally filed as 4 CSR 220-5.060. Original rule filed Jan. 3, 1992, effective Aug. 6, 1992. Moved to 20 CSR 2220-5.060, effective Aug. 28, 2006.*

*\*Original authority: 338.350, RSMo 1989.*

## **20 CSR 2220-5.070 Standards of Operation for Medical Gas Distributors**

*PURPOSE: This rule establishes standards of operation for medical gas distributors. This proposed rule has been reviewed by the Drug Distributor Advisory Committee as required by section 338.140.4, RSMo.*

(1) Medical gases are defined as compressed gases and liquid gases that a distributor or manufacturer has labeled for medical use in compliance with federal law.

(2) Medical gas distributor is defined as an entity which is licensed by the board as a drug distributor and is involved in the distribution of medical gases and related medical devices pursuant to a medical gas order to medical gas suppliers and other entities that are registered, licensed or permitted to use, administer or distribute medical gases.

(3) Medical gas distributors that are not involved in the storage or transfer of any other federal legend drugs and only store, transfer or transfill medical grade gas products other than nitrous oxide are exempt from the following regulation sections: 20 CSR 2220-5.030(3)(B); (3)(C)4., 9., 12., and 13.; (3)(E); and (3)(M)4. Medical gas distributors that store, transfer or transfill nitrous oxide are exempt from 20 CSR 2220-5.030(3)(B); (3)(C)4. and 9.; (3)(E) and (3)(M)4. All other drug distributor requirements contained within the board's regulations shall be considered applicable to medical gas distributors.

(4) A medical gas distributor that is involved in the manufacture/transfilling of medical gases must register with the Food and Drug Administration (FDA) as a medical gas manufacturer and comply with the drug listing requirements of the federal act. In addition, all current good manufacturing practice requirements as set forth in 21 CFR 210 through 211 must be complied with.

*AUTHORITY: sections 338.050, 338.333, 338.335, 338.337, and 338.340, RSMo 2000.\* This rule originally filed as 4 CSR 220-5.070. Original rule filed March 15,*

*2000, effective Sept. 30, 2000. Moved to 20 CSR 2220-5.070, effective Aug. 28, 2006. Amended: Filed Feb. 6, 2008, effective Aug. 30, 2008.*

*\*Original authority: 338.050, RSMo 1939, amended 1949, 1961, 1971, 1981; 338.333, RSMo 1989; 338.335, RSMo 1998; 338.337, RSMo 1989; and 338.340, RSMo 1989.*



20 CSR 2220-6



**Title 20—DEPARTMENT OF  
INSURANCE, FINANCIAL  
INSTITUTIONS AND  
PROFESSIONAL REGISTRATION  
Division 2220—State Board of Pharmacy  
Chapter 6—Pharmaceutical Care  
Standards**

**20 CSR 2220-6.030 Provision of Drug and/or Medical Information**

*PURPOSE: The purpose of this rule is to define requirements for the provision of drug and/or medical information by pharmacists.*

(1) Section 338.095.3., RSMo provides in part that a pharmacist may lawfully provide prescription or medical information to a licensed health care provider or his/her agent who is legally qualified to administer medications and treatments and who is involved in the treatment of the patient. The information may be derived through direct contact with a prescriber or through a written, agreed upon protocol or standing prescription order from an authorized prescriber.

(2) Information transfers as described in section (1) may take place within any practice setting as long as the pharmacist maintains an active license with the Board of Pharmacy.

(3) Information transfers between two (2) licensed pharmacists may occur as long as the pharmacist receiving that information documents in a uniform and readily retrievable fashion, the identity of the pharmacist providing the information transfer, the origin of his/her authority to provide the drug or medical information, the date and the identity of the receiving pharmacist.

(4) When a transfer of prescription information for the purpose of filling an original prescription occurs, all provisions of 4 CSR 220-2.120 must be followed, except for subsection (1)(C) and paragraphs (2)(B)4.-6.

(5) Any laws governing prescription records, dispensing procedures and controlled substances must be adhered to when a transfer of prescription information for the purpose of filling an original prescription occurs.

*AUTHORITY: sections 338.095, RSMo Supp. 1993, 338.010, RSMo Supp. 1990, 338.140, RSMo Supp. 1989 and 338.280, RSMo 1986. \* This rule originally filed as 4 CSR 220-6.030. Original rule filed March 1, 1994, effective Sept. 30, 1994. Moved to 20 CSR 2220-6.030, effective Aug. 28, 2006.*

*\*Original authority: 338.280, RSMo 1951, amended 1971, 1981; 338.010, RSMo 1939, amended 1951, 1989, 1990; and 334.104.4. and 338.095, RSMo 1993.*

**20 CSR 2220-6.040 Administration by Medical Prescription Order**

*PURPOSE: This rule establishes procedures for pharmacists to administer drugs and devices pursuant to medical prescription orders.*

(1) A pharmacist may administer drugs pursuant to a medical prescription order.

(2) The pharmacist may not delegate the administration to another person, except to a pharmacist intern who has met qualifications under subsections (3)(B), (C), and (E) and is working under the direct supervision of a pharmacist qualified to administer drugs pursuant to a medical prescription order.

(3) Pharmacist Qualifications. A pharmacist who is administering drugs pursuant to a medical prescription order must—

(A) Hold a current, unrestricted license to practice pharmacy in this state;

(B) Hold a current provider level cardiopulmonary resuscitation (CPR) certification issued by the American Heart Association or the American Red Cross or equivalent;

(C) Successfully complete a certificate program in the administration of drugs accredited by the Accreditation Council for Pharmacy Education (ACPE) or a similar health authority or professional body approved by the State Board of Pharmacy. The certificate program must cover all routes of administration the pharmacist utilizes;

(D) Complete a minimum of two (2) hours of continuing education per calendar year related to administration of drugs. A pharmacist may use the continuing education hours required in this subsection as part of the total continuing education hours required for pharmacist license renewal;

(E) Maintain documentation of the above requirements; and

(F) On a yearly basis prior to administering drugs, notify the State Board of Pharmacy of their qualifications to do so. This notification shall include the types of drugs being administered, and a statement that the pharmacist meets the requirements of subsections (A), (B), (C), and (D) of this section.

(4) General Requirements.

(A) A pharmacist shall administer drugs in accordance with treatment guidelines established by the Centers for Disease Control and Prevention (CDC) or in accordance with manufacturer's guidelines.

(B) A pharmacist shall comply with all state and federal laws and regulations pertaining to Vaccine Information Statements and informed consent requirements.

(C) A pharmacist shall have a written policy and procedure covering all aspects of the administration of drugs,

including the disposal of used and contaminated supplies and appropriate handling of acute adverse events. The manual shall be reviewed annually and be available for inspection by the State Board of Pharmacy or authorized representative.

(5) Requirements of Medical Prescription Order. The medical prescription order from a licensed prescriber must contain at a minimum the following:

(A) The name of the licensed prescriber issuing the order;

(B) The name of the patient to receive the drug;

(C) The name of the drug and dose to be administered;

(D) The route of administration;

(E) The date of the original order;

(F) The date or schedule, if any, of each subsequent administration; and

(G) A statement that the drug is to be administered by a pharmacist.

(6) Record Keeping.

(A) A pharmacist who administers a drug pursuant to a medical prescription order shall maintain the following records regarding each administration. These records must be separate from the prescription files of a pharmacy.

1. The name, address, and date of birth of the patient;
2. The date, route, and anatomic site of the administration;

3. The name, dose, manufacturer, lot number, and expiration date of the drug;

4. The name and address of the patient's primary health care provider, as identified by the patient;

5. The name or identifiable initials of the administering pharmacist; and

6. The nature of an adverse reaction and who was notified, if applicable.

(B) All records required by this regulation shall be kept by the pharmacist and be available for two (2) years from the date of such record for inspecting and copying by the State Board of Pharmacy and/or its authorized representatives.

(7) Notification Requirements.

(A) A pharmacist administering drugs pursuant to a medical prescription order shall notify the prescriber within seventy-two (72) hours after administration of the following:

1. The identity of the patient;

2. The identity of the drug administered;

3. The route of administration;

4. The anatomic site of the administration;

5. The dose administered; and

6. The date of administration.

(B) In the event of any adverse event or reaction experienced by the patient, the pharmacist shall notify the prescriber within twenty-four (24) hours after learning of the adverse event or reaction.

(C) A pharmacist administering drugs pursuant to a medical prescription order shall report the administration to all entities as required by state or federal law.

*AUTHORITY: sections 338.140 and 338.280, RSMo 2000 and section 338.010.1, RSMo Supp. 2007.\* Emergency rule filed May 1, 2008, effective May 11, 2008, expired Feb. 18, 2009. Original rule filed May 1, 2008, effective Nov. 30, 2008.*

*\*Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007; 338.140, RSMo 1939, amended 1981, 1989, 1997; and 338.280, RSMo 1951, amended 1971, 1981.*

## **20 CSR 2220-6.050 Administration of Vaccines Per Protocol**

*PURPOSE: This rule establishes the procedures for pharmacists to administer vaccines per written protocol with a physician.*

(1) A pharmacist may administer vaccines authorized by Chapter 338, RSMo, pursuant to a written protocol authorized by a physician licensed pursuant to Chapter 334, RSMo, who is actively engaged in the practice of medicine.

(A) A pharmacist shall administer vaccines in accordance with treatment guidelines established by the Centers for Disease Control (CDC) and in accordance with manufacturer's guidelines, provided that a pharmacist shall not administer vaccines to persons under twelve (12) years of age.

(B) A pharmacist shall comply with all state and federal laws and regulations pertaining to Vaccine Information Statements and informed consent requirements.

(2) A pharmacist may not delegate the administration of vaccines to another person, except to a pharmacist intern who has met the qualifications under subsections (4)(B), (C), and (D) and is working under the direct supervision of a pharmacist qualified to administer vaccines.

(3) The authorizing physician is responsible for the oversight of, and accepts responsibility for, the vaccines administered by the pharmacist.

(4) Pharmacist Qualifications. A pharmacist who is administering a vaccine authorized by Chapter 338, RSMo, must:

(A) Hold a current, unrestricted license to practice pharmacy in this state;

(B) Hold a current cardiopulmonary resuscitation (CPR) certification issued by the American Heart Association or the American Red Cross or equivalent;

(C) Successfully complete a certificate program in the administration of vaccines accredited by the Accreditation Council for Pharmacy Education (ACPE) or a similar health authority or professional body approved by the

State Board of Pharmacy;

(D) Maintain documentation of the above certifications;

(E) Complete a minimum of two (2) hours (0.2 CEU) of continuing education as defined per calendar year related to administration of vaccines. A pharmacist may use the continuing education hours required in this subsection as part of the total continuing education hours required for pharmacist license renewal;

(F) Provide documentation of subsections (A), (B), (C), and (E) of this section to the authorizing physician(s) prior to entering into a protocol or administering vaccines; and

(G) On a yearly basis prior to administering vaccines, establish a new protocol with the authorizing physician and notify the State Board of Pharmacy of their qualifications to do so. This notification shall include the types of drugs being administered and a statement that the pharmacist meets the requirements of subsections (A), (B), (C), (E), and (F) of this section.

(5) Administration by Written Protocol with a Missouri Licensed Physician.

(A) A pharmacist may enter into a written protocol with a physician for the administration of vaccines authorized by Chapter 338, RSMo, provided that a pharmacist shall be prohibited from administering vaccines to patients under twelve (12) years of age. The physician must be no further than fifty (50) miles by road, using the most direct route available, from the pharmacist who is administering the vaccine. The written protocol may be valid for a time period not to exceed one (1) year. The protocol must include the following:

1. The identity of the participating pharmacist and physician, including signatures;

2. Time period of the protocol;

3. The identification of the vaccines which may be administered;

4. The identity of the patient or groups of patients to receive the authorized vaccine(s);

5. The identity of the authorized routes and anatomic sites of administration allowed;

6. A provision to create a prescription for each administration under the authorizing physician's name;

7. A provision establishing a course of action the pharmacist shall follow to address emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks;

8. A provision establishing a length of time the pharmacist shall observe an individual for adverse events following an injection;

9. A provision establishing the disposal of used and contaminated supplies;

10. The street addresses of the pharmacy or other locations at which the pharmacist may administer the authorized vaccine;

11. Record-keeping requirements and procedures for notification of administration; and

12. A provision that allows for termination of the protocol at the request of any party to it at any time.

(B) The protocol, and any subsequent amendments or alterations, shall be signed and dated by the pharmacist and authorizing physician prior to its implementation, signifying that both are aware of its content and agree to follow the terms of the protocol. The authorizing physician and pharmacist shall each maintain a copy of the protocol from the beginning of implementation to a minimum of eight (8) years after termination of the protocol.

(6) Record Keeping.

(A) A pharmacist administering vaccines pursuant to this rule shall maintain a record of each administration which shall include:

1. The name, address, and date of birth of the patient;

2. The date, route, and anatomic site of the administration;

3. The name, dose, manufacturer, lot number, and expiration date of the vaccine;

4. The name and address of the patient's primary health care provider, as identified by the patient;

5. The name or identifiable initials of the administering pharmacist; and

6. The nature of an adverse reaction and who was notified, if applicable.

(B) If the vaccine was administered on behalf of a pharmacy, the pharmacist shall ensure the records required by subsection (6)(A) of this rule are promptly delivered to the pharmacy.

(C) Within seventy-two hours (72) hours after administration of a vaccine, the administering pharmacist shall obtain a prescription from the authorizing physician for the drug dispensed or shall create a prescription, as authorized by protocol documenting the dispensing of the drug. Notwithstanding any other provision of this rule, prescription records shall be maintained as provided by Chapter 338, RSMo, and the rules of the board.

(D) The records required by this rule shall be maintained securely and confidentially as follows:

1. If the vaccine is administered on behalf of a pharmacy, both the pharmacy and the administering pharmacist shall ensure that all records required by this rule are maintained at the pharmacy separate from the prescription files of the pharmacy. If the vaccine is not being administered on behalf of a pharmacy, all records shall be maintained securely and confidentially by the administering pharmacist at an address that shall be identified in the protocol prior to administering the vaccine; and

2. Records shall be maintained for two (2) years from the date of such record and shall be made available for inspecting and copying by the State Board of Pharmacy or the State Board of Registration for the Healing Arts and/or their authorized representatives. Records maintained at a pharmacy must be produced during an inspection by the board and/or their authorized representatives. Records not maintained at a pharmacy shall be produced within three (3) business days after a request

from the State Board of Pharmacy and/or its authorized representative. Failure to maintain or produce records as provided by this rule shall constitute grounds for discipline.

(7) Notification Requirement.

(A) A pharmacist administering vaccines authorized by Chapter 338, RSMo, shall notify the authorizing physician within seventy-two (72) hours after administration of the following:

1. The identity of the patient;
2. The identity of the vaccine(s) administered;
3. The route of administration;
4. The anatomic site of the administration;
5. The dose administered; and
6. The date of administration.

(B) The pharmacist shall provide a written report to the patient's primary health care provider, if different than the authorizing physician, containing the documentation required in subsection (A) of this section within fourteen (14) days of the administration.

(C) In the event of any adverse event or reaction experienced by the patient pursuant to a written protocol, the pharmacist shall notify the patient's primary health care provider and authorizing physician, if different, within twenty-four (24) hours after learning of the adverse event or reaction.

(D) A pharmacist administering vaccine(s) shall report the administration to all entities as required by state or federal law.

(E) Documentation that notifications required by this rule have been sent must be maintained as provided in section (6) of this rule.

*AUTHORITY: sections 338.010 and 338.220, RSMo Supp. 2009 and 338.140, RSMo 2000.\* Emergency rule filed Oct. 24, 2007, effective Nov. 3, 2007, expired April 30, 2008. Original rule filed Oct. 24, 2007, effective May 30, 2008. Emergency amendment filed Oct. 22, 2009, effective Nov. 1, 2009, expired April 29, 2010. Amended: Filed Oct. 22, 2009, effective June 30, 2010.*

*Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009; 338.140, RSMo 1939, amended 1981, 1989, 1997; and 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997, 1999, 2001, 2004, 2007, 2009.*

## **20 CSR 2220-6.055 Non-Dispensing Activities**

*PURPOSE: This rule establishes procedures and requirements for the performance of non-dispensing activities outside of a pharmacy.*

(1) Pursuant to section 338.220, RSMo, a pharmacist may perform the following non-dispensing activities outside of a licensed pharmacy:

(A) Patient counseling/education, as authorized by Missouri law, provided the pharmacist shall be obligated to comply with 20 CSR 2220-2.190, when applicable;

(B) Obtain patient history/information;

(C) Review patient records/medical histories;

(D) Patient assessment/evaluation, as authorized by Missouri law;

(E) Billing and insurance claim submissions/review;

(F) Drug utilization review;

(G) Assess health plan and medication eligibility/coverage;

(H) Pharmacy compliance audits/evaluations;

(I) Administer drugs, vaccines, or biologicals, as authorized by law and the rules of the board;

(J) Peer review/peer consultations;

(K) Review, select, and develop formularies or plan/practice guidelines;

(L) Review compliance with benefit guidelines;

(M) Manage inventory, including purchasing and ordering;

(N) Manage/review information systems;

(O) Patient medication review;

(P) Consultation with other health care professionals;

(Q) Patient referrals;

(R) Prescription order entry/review, provided that a pharmacist shall only be authorized to accept a prescription on the premises of a Missouri licensed pharmacy, as required by section 338.095.5, RSMo; and

(S) Medication therapy management, pursuant to and as authorized by Chapter 338, RSMo, and the rules of the board.

(2) Confidentiality. A pharmacist performing non-dispensing activities pursuant to this rule shall comply with all applicable state and federal confidentiality laws and regulations and shall provide sufficient storage and security for confidential documents and electronic data processing hardware. In addition, data processing systems must utilize sufficient security software to ensure confidentiality and prevent unauthorized access. Any breach in the security or confidentiality of the data processing systems or confidential documents shall be documented and reported to the board in writing within seven (7) days of the breach.

(3) Notwithstanding any other provision of this rule, a pharmacist shall not meet with patients in the pharmacist's residence or living quarters.

(4) A pharmacist performing non-dispensing activities pursuant to this rule shall ensure compliance with Chapter 338, RSMo, and the rules of the board at all times. Nothing in this rule shall be construed to eliminate or otherwise exempt any pharmacist from the record-keeping, confidentiality, or security requirements otherwise imposed by Chapter 338, RSMo, or the rules of the board. Violations of this section shall constitute grounds for discipline.

(5) This rule shall not be construed to authorize a pharmacist to conduct the unauthorized practice of medicine

or to conduct any activity for which a license is required pursuant to Chapters 330, 331, 332, 334, or 337, RSMo.

(6) A pharmacy permit shall be required for performing non-dispensing activities if the pharmacist is using a pharmacy technician to assist in the practice of pharmacy at the location where non-dispensing activities are being performed, provided that a pharmacy permit shall not be required for sites used solely by the pharmacist for administering vaccines as authorized by Chapter 338, RSMo, and the rules of the board. Pharmacy technicians shall only be authorized to work under the direct supervision of a pharmacist as provided by section 338.013, RSMo, and 20 CSR 2220-2.700.

*AUTHORITY: sections 338.010 and 338.220, RSMo Supp. 2009 and 338.140, RSMo 2000.\* Emergency rule filed Oct. 23, 2009, effective Nov. 2, 2009, expired April 30, 2010. Original rule filed Oct. 22, 2009, effective June 30, 2010.*

*\*Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009; 338.140, RSMo 1939, amended 1981, 1989, 1997; and 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997, 1999, 2001, 2004, 2007, 2009.*

## **20 CSR 2220-6.060 General Provisions**

*PURPOSE: This rule establishes definitions for 20 CSR 2220-6.060 to 20 CSR 2220-6.080 governing medication therapy services by pharmacists.*

(1) Definitions. The following definitions shall apply for purposes of 20 CSR 2220-6.060 to 20 CSR 2220-6.080:

(A) Authorizing physician(s)—The physician identified in the written protocol as authorizing the pharmacist to provide medication therapy services;

(B) Health care entity—For purposes of this rule, a health care entity shall be defined as any entity or organization that is licensed or certified by the state or federal government as a hospital, hospice facility, ambulatory surgical center, nursing home, long-term care facility, residential care facility, assisted living facility, intermediate care facility, skilled nursing facility, or a habilitation center as defined by Chapter 630, RSMo, and that is required to maintain patient medical records by state or federal law;

(C) Medication therapy protocol—A written agreement between a physician and a pharmacist for the provision of medication therapy services. A medication therapy protocol shall comply with the provisions of 20 CSR 2220-6.080;

(D) Medication therapy services—The designing, initiating, implementing, or monitoring of a plan to monitor the medication therapy or device usage of a specific patient, or to enhance medication therapeutic outcomes of a specific patient, by a pharmacist who has authority to initiate or implement a modification of the patient's medication therapy or device usage pursuant to a medi-

cation therapy protocol. For purposes of 20 CSR 2220-6.060 to 20 CSR 2220-6.080, modification shall include selecting a new, different, or additional medication or device, discontinuing a current medication or device, or selecting a new, different, or additional strength, dose, dosage form, dosage schedule, or route of administration for a current medication or device, and implementing such selection(s). Medication therapy services shall not include the sole act of dispensing a drug or device pursuant to a valid prescription for the product, generic substitutions made pursuant to section 338.056, RSMo, or medication therapy management that does not include the initiation or implementation of a modification of medication therapy, as provided herein;

(E) Pharmacy resident—A Missouri-licensed pharmacist enrolled in a residency training program accredited by the American Society of Health-System Pharmacists or a residency training program with a valid application for accreditation pending with the American Society of Health-System Pharmacists;

(F) Prescription order for medication therapeutic plan—A lawful order that is issued by the authorizing physician within the scope of his/her professional practice for the provision of medication therapy services by a pharmacist for a specific patient, including, patients of a health care entity; and

(G) Protocol—A medication therapy protocol, as defined herein.

(2) The provisions of 20 CSR 2220-6.060 to 20 CSR 2220-6.080 and 20 CSR 2150-5.026 to 20 CSR 2150-5.028 shall only be deemed applicable to persons or entities under the jurisdiction of the Missouri State Board of Pharmacy and the Missouri State Board of Registration for the Healing Arts, as established by Chapter 338, RSMo, and Chapter 334, RSMo.

*AUTHORITY: sections 338.010, 338.140.1., and 338.380, RSMo Supp. 2011.\* Original rule filed Jan. 13, 2012, effective Aug. 30, 2012.*

*\*Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; and 338.380, RSMo 2007.*

## **20 CSR 2220-6.070 Certificate of Medication Therapeutic Plan Authority**

*PURPOSE: This rule establishes procedures for obtaining a certificate of medication therapeutic plan authority, as authorized by section 338.010, RSMo.*

(1) A pharmacist shall obtain a certificate of medication therapeutic authority from the Missouri State Board of Pharmacy to provide medication therapy services that include initiating or implementing a modification of a patient's medication therapy or device usage. Pharmacists with a certificate of medication therapeutic authority shall enter into a written protocol with a Missouri-li-

censed physician that complies with the requirements of 20 CSR 2220-6.080, prior to performing medication therapy services.

(2) Applicants for certification shall hold an active Missouri pharmacist license. Applications shall be submitted on forms provided by the Missouri State Board of Pharmacy and shall be accompanied by the certificate of medication therapeutic plan authority fee and proof the applicant—

(A) Holds a doctor of pharmacy (PharmD) degree earned from a school, accredited by the Accreditation Council for Pharmacy Education (ACPE); or

(B) Has successfully completed a post-graduate medication therapy certificate course or program accredited or granted by the APCE, American Society of Health-System Pharmacists, American Society of Consultant Pharmacists, or the American Pharmacists Association; or

(C) Holds a current certification from the Board of Pharmaceutical Specialties, the Commission for Certification in Geriatric Pharmacy, or the National Certification Board for Diabetes Educators; or

(D) Has completed a post-graduate medication therapy certificate course that, at a minimum, included training in the following areas:

1. Assessing patient specific data and issues;
2. Establishing medication therapeutic goals or medication related action plans for identified medication conditions and medication related concerns;
3. Assessing and addressing adverse reactions and adverse drug events;
4. Modifying and monitoring medication regimens;
5. Improving patient care and outcomes through medication therapy services;
6. Evaluating treatment progress;
7. Assessing and monitoring pharmacokinetic and pharmacodynamic changes in medication regimen reviews;
8. Medication reconciliation;
9. Drug utilization review;
10. Applicable state or federal law;
11. Formulating and documenting personal medication records;
12. Documenting clinical outcomes;
13. Interpreting, monitoring, ordering, and assessing patient test results; and
14. Patient education and counseling.

(3) Certificate Renewal. A certificate of medication therapeutic plan authority shall be renewed biennially with the certificate holder's Missouri pharmacist license. For purposes of renewal, six (6) of the continuing education hours required for renewing the certificate holder's Missouri pharmacist license shall be earned in courses/programs related to medication therapy management. The continuing education required by this rule shall be governed by the rules of the Missouri State Board of Pharmacy governing pharmacist continuing education.

(4) The Missouri State Board of Pharmacy may discipline or terminate a pharmacist's certificate of medication therapeutic plan authority if the Missouri State Board of Pharmacy determines that the pharmacist has violated the terms of a protocol, the requirements of Chapter 338, RSMo, or rules of the board governing medication therapy services or any other state or federal drug law.

*AUTHORITY: sections 338.010, 338.140.1., and 338.380, RSMo Supp. 2011.\* Original rule filed Jan. 13, 2012, effective Aug. 30, 2012.*

*\*Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; and 338.380, RSMo 2007.*

## **20 CSR 2220-6.080 Medication Therapy Services By Protocol**

*PURPOSE: This rule establishes procedures for the provision of medication therapy services by protocol, as authorized by section 338.010, RSMo.*

(1) Except as otherwise provided herein, a pharmacist who holds a certificate of medication therapeutic plan authority from the Missouri State Board of Pharmacy shall be authorized to provide medication therapy services in Missouri if the pharmacist—

(A) Holds a current Missouri pharmacist license that is not under discipline with the Missouri State Board of Pharmacy; and

(B) Has entered into a written protocol with a Missouri licensed physician that complies with the requirements of this rule.

(2) General Requirements. A pharmacist may provide medication therapy services only with current certification and as authorized by the protocol and the authorizing physician. A pharmacist providing medication therapy services pursuant to this rule shall comply with the following:

(A) Prior to providing medication therapy services, the pharmacist shall receive a prescription order for a medication therapeutic plan from the authorizing physician for a specific patient which authorizes the pharmacist to perform medication therapy services. Except as otherwise provided in subsection (2)(B) of this rule, the prescription order for a medication therapeutic plan shall be valid for no more than one (1) year and shall include:

1. The patient's name, address, and date of birth;
2. The date the prescription order for a medication therapeutic plan is issued;
3. The clinical indication for medication therapy services;
4. The length of time for providing medication therapy services, if less than one (1) year; and
5. The authorizing physician's name and address;

(B) A prescription order for a medication therapeutic



plan may be transmitted orally, electronically, or in writing. If an oral prescription order for a medication therapeutic plan is issued, all information required under subsection (2)(A) of this rule shall be documented by the pharmacist and maintained in the patient's record in accordance with section (7) of this rule;

(C) The pharmacist shall review relevant prescription records, patient profiles, patient medical records, or other medical information to determine the services to be rendered; and

(D) In lieu of compliance with 20 CSR 2220-2.018, prescription orders for medication therapy services shall comply with the provisions of this rule, provided the pharmacist shall maintain the prescription order in the patient record required by section (7) of this rule and shall document any change or alteration made to the prescription ordered based on contact with the prescriber in the applicable patient record.

### (3) Authorizing Physician Requirements.

(A) The authorizing physician shall be actively engaged in the practice of medicine in the state of Missouri and shall hold a current and unrestricted Missouri physician license pursuant to Chapter 334, RSMo.

(B) The authorizing physician shall be responsible for the oversight of the medication therapy services provided by the pharmacist that are authorized by protocol. The authorizing physician shall also consider the level of skill, education, training, and competence of the pharmacist and ensure that the activities authorized by the protocol are consistent with the pharmacist's level of skill, education, training, and competence.

(C) The written protocol shall be reviewed and signed by the pharmacist and the authorizing physician at least annually and revised as needed. The authorizing physician and pharmacist shall document the date of the annual review on the written protocol.

(D) The authorizing physician shall review the pharmacist's medication therapy service activities regularly, but not less than once every three (3) months. If the pharmacist is providing medication therapy services for, or on behalf of, a health care entity, the review requirements shall be satisfied if the pharmacist's work and services are reviewed every three (3) months by a clinical care committee, pharmacy and therapeutics committee, or a reviewing body/committee of the health care entity that includes a Missouri-licensed physician. The review required by this subsection may be accomplished in person or by electronic means.

(E) The practice location of the authorizing physician shall be no further than fifty (50) miles by road from the pharmacist identified in the written protocol.

(F) An authorizing physician shall notify the Missouri State Board of Registration for the Healing Arts of a written protocol for medication therapy services entered with a pharmacist at each renewal of the authorizing physician's license.

### (4) Protocol Requirements.

(A) The medication therapy services performed by a pharmacist pursuant to the protocol shall be within the authorizing physician's scope of practice and within the skill, education, training, and competence of both the authorizing physician and the pharmacist.

(B) The written protocol between the authorizing physician and pharmacist shall, at a minimum, include the following:

1. The identity and signatures of the authorizing physician and pharmacist;

2. The effective dates of the protocol;

3. A statement of clinical conditions, diagnoses, diseases, and specific drugs, or drug categories included in the written protocol and the type of medication therapy services allowed in each case;

4. A statement of the methods, procedures, decision criteria, and plan the pharmacist is to follow when conducting medication therapy services;

5. Procedures for documenting medication therapy decisions made by the pharmacist and a plan for communication, feedback, and reporting to the authorizing physician concerning specific decisions made;

6. A mechanism and procedure that allows the authorizing physician to override, rescind, modify, or otherwise amend the protocol. All modifications or amendments to the protocol shall be documented in writing, signed, and dated by all involved parties prior to the implementation of such modification or amendment. The protocol may be immediately rescinded by the authorizing physician or the pharmacist with or without cause, provided the rescission is documented in writing. If any conflict arises regarding the professional judgment of the pharmacist and physician with regard to the subject of the medication therapy services, the physician has ultimate authority;

7. A statement that the pharmacist shall not delegate the responsibility of medication therapy services to another person;

8. A description of any authority granted to the pharmacist to administer any drug or medication including the identification of any such drug, medication, or device;

9. A description of drug therapy related patient assessment procedures or testing that may be ordered or performed by the pharmacist, including any authority to order or perform routine or other laboratory testing;

10. Provisions for allowing the pharmacist to access the patient's medical records for purposes of providing medication therapy services;

11. A provision for providing the authorizing physician access to patient records for medication therapy services provided by the pharmacist for patients of the authorizing physician;

12. Provisions establishing a course of action the pharmacist is authorized to follow to address emergency situations, including, but not limited to, anaphylactic or other adverse medication reactions, adverse needle

sticks, or other adverse events;

13. Criteria for timely communication from the authorizing physician to the pharmacist and from the pharmacist to the authorizing physician, not inconsistent with the provisions of this rule;

14. The notification requirements required by section (5) of this rule; and

15. The method for reviewing the pharmacist's medication therapy work or services by the authorizing physician, as required by subsection (3)(D) of this rule.

(C) The written protocol shall include a description of medication therapy services the pharmacist is authorized to render or provide. Such services may include:

1. Assessing patient-specific data and issues;
2. Establishing medication therapeutic goals or medication related action plans for identified medical conditions and medication related concerns;
3. Assessing and addressing adverse reactions and adverse drug events;
4. Modifying and monitoring medication regimens;
5. Evaluating treatment progress;
6. Assessing and monitoring pharmacokinetic and pharmacodynamic changes in medication regimen reviews;
7. Medication reconciliation;
8. Drug utilization review;
9. Formulating and documenting personal medication records;
10. Documenting clinical outcomes;
11. Interpreting, monitoring, and assessing patient test results;
12. Initiation of drug therapy, as authorized by protocol; and
13. Patient education and counseling.

(D) The protocol required by this section shall be signed and dated by the authorizing physician and the pharmacist. If the protocol includes multiple authorizing physicians or participating pharmacists, a separate protocol shall not be required for each physician or pharmacist if all authorizing physicians and pharmacists have signed and dated a statement agreeing to be governed by the terms of the written protocol.

(E) Any revisions, modifications, or amendments to the protocol must be in writing. The authorizing physician shall promptly notify the pharmacist of any such revision, modification, or amendment and shall maintain documentation of the notification, including the date such notification was made. The authorizing physician may delegate the notification requirements of this subsection to an authorized designee, provided the physician shall be ultimately responsible for compliance with the notification requirements.

(F) A pharmacist shall not be authorized to adjust, change, or modify any controlled substance prescribed for a patient, except as authorized by state or federal law.

(G) The protocol shall be maintained by the authorizing physician and the pharmacist for a minimum of eight (8)

years after termination of the protocol. The protocol may be maintained electronically.

(H) A protocol shall automatically and immediately terminate if the pharmacist ceases to maintain an active Missouri pharmacist license, the authorizing physician is deceased, or if the authorizing physician fails to maintain an active, unrestricted Missouri physician license.

(I) Pharmacy Residents. If specifically authorized by the protocol, a pharmacy resident shall be authorized to perform medication therapy services under the written protocol of a Missouri pharmacist in lieu of an individual protocol, if—

1. The resident holds a certificate of medication therapeutic plan authority from the Missouri State Board of Pharmacy;

2. The resident is enrolled in a residency training program accredited by the American Society of Health-System Pharmacists or a residency training program with a valid application for accreditation pending with the American Society of Health-System Pharmacists; and

3. The resident is providing medication therapy services under the supervision of a Missouri pharmacist certified by the Missouri State Board of Pharmacy to perform medication therapy services.

(J) The provisions of subsection (4)(I) shall only apply to medication therapy services provided by a pharmacist as part of his/her residency training.

(5) Notification Requirements. A pharmacist shall comply with the following notification requirements:

(A) Within twenty-four (24) hours after learning of an anaphylactic or other adverse medication reaction, adverse needle stick, or other adverse event experienced by a patient, the pharmacist shall notify the patient's authorizing physician or an authorized designee of the authorizing physician;

(B) The pharmacist shall notify the authorizing physician or an authorized designee of the authorizing physician in the written protocol of any modification of therapy, within twenty-four (24) hours, provided the protocol may include more stringent notification requirements;

(C) A pharmacist shall be deemed in compliance with the notification requirements of this rule if the pharmacist is providing medication therapy services for, or on behalf of, a health care entity, as defined by this rule, and documentation of the notifications required by this section is recorded in a patient medical record that is required to be maintained by the health care entity pursuant to state or federal law; and

(D) Notifications required by this section shall be in writing unless otherwise authorized by the authorizing physician.

(6) Modifying Drug Therapy.

(A) A pharmacist may be authorized by protocol to modify a patient's non-controlled substance medication therapy, subject to the following:

1. If the pharmacist modifies medication therapy and a

medication or device is to be dispensed, the pharmacist shall create a prescription for the medication or device modified under the authorizing physician's name. Such prescription may be dispensed by a licensed pharmacy and shall be maintained in the prescription records of the dispensing pharmacy as provided by the rules of the Missouri State Board of Pharmacy; and

2. If the pharmacist modifies medication therapy or a device, the pharmacist shall document such modification according to section (7) of this rule. Pharmacists providing medication therapy services for patients of a health care entity shall be deemed in compliance with the provisions of this subsection if the modification is documented in a patient medical record that the health care entity is required to maintain under state or federal law.

(B) The pharmacist shall not modify any controlled substance prescription. A prescription from the authorizing physician shall be required to modify a controlled substance.

(C) For purposes of 20 CSR 2220-6.060, 20 CSR 2220-6.070, and 20 CSR 2220-6.080, modification of medication therapy shall include selecting a new, different, or additional medication or device, discontinuing a current medication or device, or selecting a new, different, or additional strength, dose, dosage form, dosage schedule, or route of administration for a current medication or device, and implementing such selection(s). Medication therapy services shall not include the sole act of dispensing a drug or device pursuant to a valid prescription for the product or generic substitutions made pursuant to section 338.056, RSMo.

#### (7) Record Keeping.

(A) A pharmacist shall document and maintain an adequate patient record of medication therapy services provided to each patient. The records may be maintained in electronic format provided the records are capable of being printed for review by the Missouri State Board of Registration for the Healing Arts and the Missouri State Board of Pharmacy. An adequate and complete patient record shall include documentation of the following:

1. The identification of the patient, including, name, birthdate, address, and telephone number;
2. The date(s) of any patient visit or consultation, including the reason for any such visit/consultation;
3. Any pertinent assessments, observations, or findings;
4. Any diagnostic testing recommended or performed;
5. The name of any medication or device modified and the strength, dose, dosage schedule, dosage form, and route of administration of any medication modified or administered;
6. Referrals to the authorizing physician;
7. Referrals for emergency care;
8. Any contact with the authorizing physician concerning the patient's treatment or medication therapy services plan;

9. Any informed consent for procedures, medications, or devices; and

10. Any consultation with any other treatment provider for the patient and the results of such consultation.

(B) Pharmacist Record Retention. Except as otherwise provided herein, records required to be maintained by a pharmacist pursuant to this rule shall be maintained securely and confidentially for a minimum of seven

(7) years after termination of the protocol unless more stringent requirements are established for record keeping under state or federal law. All records required to be maintained by the pharmacist by this rule shall be maintained by the pharmacist at an address that shall be identified in the written protocol.

(C) Physician Record Retention. Except as otherwise provided herein, records required to be maintained by the authorizing physician pursuant to this rule shall be maintained securely and confidentially for a minimum of seven (7) years after termination of the protocol unless more stringent requirements are established for record keeping pursuant to state or federal law.

(8) Production of Records. Records maintained at a pharmacy must be produced during an inspection or investigation by the Missouri State Board of Pharmacy, Missouri State Board of Registration for the Healing Arts, or their authorized representatives, as requested by the respective board or the board's designee. Records not maintained at a pharmacy shall be produced within three (3) business days after a request from the Missouri State Board of Pharmacy, Missouri State Board of Registration for the Healing Arts, and/or its authorized representative. Failure to maintain or produce records as provided by this rule shall constitute grounds for discipline.

(9) Nothing in this rule shall be construed to permit medical diagnosis of any condition by a pharmacist or the independent issuing of a prescription by a pharmacist.

(10) A pharmacist shall not violate or practice in a manner inconsistent with the provisions of this rule or a written protocol. A pharmacist's failure to abide by the requirements of this rule or the provisions of a written protocol shall be subject to disciplinary action pursuant to the provisions of Chapter 338, RSMo.

(11) The requirements of this rule shall not apply to the administration of vaccines pursuant to protocol as governed by 20 CSR 2220-6.050 or the administration of medication by protocol as governed by 20 CSR 2220-6.040.

(12) The Missouri State Board of Registration for the Healing Arts and the Missouri State Board of Pharmacy separately retain the right and duty to discipline their respective licensees for violations of any state or federal statutes, rules, or regulations regardless of the licens-

ee's participation in a protocol agreement.

(13) The provisions of 20 CSR 2220-6.060 to 20 CSR 2220-6.080 and 20 CSR 2150-5.026 to 20 CSR 2150-5.028 shall only be deemed applicable to persons or entities under the jurisdiction of the Missouri State Board of Pharmacy and the Missouri State Board of Registration for the Healing Arts, as established by Chapter 338, RSMo, and Chapter 334, RSMo.

*AUTHORITY: sections 338.010, 338.140.1., and 338.380, RSMo Supp. 2011. \* Original rule filed Jan. 13, 2012, effective Aug. 30, 2012.*

*\*Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; and 338.380, RSMo 2007.*

# BNDD STATUTES



## CHAPTER 195: DRUG STATUTES (Excerpts only)

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**195.017. Substances, how placed in schedules--list of scheduled substances--publication of schedules annually--electronic log of transactions to be maintained, when--certain products to be located behind pharmacy counter--exemption from requirements, when--rulemaking authority.**

1. The department of health and senior services shall place a substance in Schedule I if it finds that the substance:

- (1) Has high potential for abuse; and
- (2) Has no accepted medical use in treatment in the United States or lacks accepted safety for use in treatment under medical supervision.

2. Schedule I:

(1) The controlled substances listed in this subsection are included in Schedule I;

(2) Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation:

- (a) Acetyl-alpha-methylfentanyl;
- (b) Acetylmethadol;
- (c) Allylprodine;
- (d) Alphacetylmethadol;
- (e) Alphameprodine;
- (f) Alphamethadol;
- (g) Alpha-methylfentanyl;
- (h) Alpha-methylthiofentanyl;
- (i) Benzethidine;
- (j) Betacetylmethadol;
- (k) Beta-hydroxyfentanyl;
- (l) Beta-hydroxy-3-methylfentanyl;
- (m) Betameprodine;
- (n) Betamethadol;
- (o) Betaprodine;
- (p) Clonitazene;
- (q) Dextromoramide;
- (r) Diampromide;
- (s) Diethylthiambutene;
- (t) Difenoxin;
- (u) Dimenoxadol;
- (v) Dimepheptanol;
- (w) Dimethylthiambutene;
- (x) Dioxaphetyl butyrate;
- (y) Dipipanone;
- (z) Ethylmethylthiambutene;
- (aa) Etonitazene;
- (bb) Etoxidine;
- (cc) Furethidine;
- (dd) Hydroxypethidine;
- (ee) Ketobemidone;
- (ff) Levomoramide;
- (gg) Levophenacymorphan;
- (hh) 3-Methylfentanyl;
- (ii) 3-Methylthiofentanyl;
- (jj) Morpheridine;
- (kk) MPPP;
- (ll) Noracymethadol;
- (mm) Norlevorphanol;
- (nn) Normethadone;
- (oo) Norpipanone;
- (pp) Para-fluorofentanyl;
- (qq) PEPAP;
- (rr) Phenadoxone;
- (ss) Phenampromide;

- (tt) Phenomorphan;
- (uu) Phenoperidine;
- (vv) Pir tramide;
- (ww) Proheptazine;
- (xx) Properidine;
- (yy) Propiram;
- (zz) Racemoramide;
- (aaa) Thiofentanyl;
- (bbb) Tilidine;
- (ccc) Trimeperidine;

(3) Any of the following opium derivatives, their salts, isomers and salts of isomers unless specifically excepted, whenever the existence of these salts, isomers and salts of isomers is possible within the specific chemical designation:

- (a) Acetorphine;
- (b) Acetyldihydrocodeine;
- (c) Benzylmorphine;
- (d) Codeine methylbromide;
- (e) Codeine-N-Oxide;
- (f) Cyprenorphine;
- (g) Desomorphine;
- (h) Dihydromorphine;
- (i) Drotebanol;
- (j) Etorphine (except hydrochloride salt);
- (k) Heroin;
- (l) Hydromorphanol;
- (m) Methyldesorphine;
- (n) Methyldihydromorphine;
- (o) Morphine methylbromide;
- (p) Morphine methylsulfonate;
- (q) Morphine-N-Oxide;
- (r) Myrophine;
- (s) Nicocodeine;
- (t) Nicomorphine;
- (u) Normorphine;
- (v) Pholcodine;
- (w) Thebacon;

(4) Any material, compound, mixture or preparation which contains any quantity of the following hallucinogenic substances, their salts, isomers and salts of isomers, unless specifically excepted, whenever the existence of these salts, isomers, and salts of isomers is possible within the specific chemical designation:

- (a) 4-bromo-2, 5-dimethoxyamphetamine;
- (b) 4-bromo-2, 5-dimethoxyphenethylamine;
- (c) 2,5-dimethoxyamphetamine;
- (d) 2,5-dimethoxy-4-ethylamphetamine;
- (e) 2,5-dimethoxy-4-(n)-propylthiophenethylamine;
- (f) 4-methoxyamphetamine;
- (g) 5-methoxy-3,4-methylenedioxyamphetamine;
- (h) 4-methyl-2, 5-dimethoxyamphetamine;
- (i) 3,4-methylenedioxyamphetamine;
- (j) 3,4-methylenedioxymethamphetamine;
- (k) 3,4-methylenedioxy-N-ethylamphetamine;
- (l) N-hydroxy-3, 4-methylenedioxyamphetamine;
- (m) 3,4,5-trimethoxyamphetamine;
- (n) 5-MeO-DMT or 5-methoxy-N,N-dimethyltryptamine, its isomers, salts, and salts of isomers;
- (o) Alpha-ethyltryptamine;
- (p) Alpha-methyltryptamine;
- (q) Bufotenine;
- (r) Diethyltryptamine;

- (s) Dimethyltryptamine;
- (t) 5-methoxy-N,N-diisopropyltryptamine;
- (u) Ibogaine;
- (v) Lysergic acid diethylamide;
- (w) Marijuana or marihuana;
- (x) Mescaline;
- (y) Parahexyl;
- (z) Peyote, to include all parts of the plant presently classified botanically as *Lophophora Williamsii* Lemaire, whether growing or not; the seeds thereof; any extract from any part of such plant; and every compound, manufacture, salt, derivative, mixture or preparation of the plant, its seed or extracts;
  - (aa) N-ethyl-3-piperidyl benzilate;
  - (bb) N-methyl-3-piperidyl benzilate;
  - (cc) Psilocybin;
  - (dd) Psilocyn;
  - (ee) Tetrahydrocannabinols naturally contained in a plant of the genus *Cannabis* (cannabis plant), as well as synthetic equivalents of the substances contained in the cannabis plant, or in the resinous extractives of such plant, or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant, such as the following:
    - a. 1 cis or trans tetrahydrocannabinol, and their optical isomers;
    - b. 6 cis or trans tetrahydrocannabinol, and their optical isomers;
    - c. 3,4 cis or trans tetrahydrocannabinol, and their optical isomers;
    - d. Any compounds of these structures, regardless of numerical designation of atomic positions covered;
  - (ff) Ethylamine analog of phencyclidine;
  - (gg) Pyrrolidine analog of phencyclidine;
  - (hh) Thiophene analog of phencyclidine;
  - (ii) 1- $\beta$ -(2-thienyl)cyclohexylpyrrolidine;
  - (jj) *Salvia divinorum*;
  - (kk) Salvinorin A;
  - (ll) Synthetic cannabinoids:
    - a. Any compound structurally derived from 3-(1-naphthoyl)indole or 1H-indol-3-yl-(1-naphthyl)methane by substitution at the nitrogen atom of the indole ring by alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent, whether or not substituted in the naphthyl ring to any extent. Including, but not limited to:
      - (i) JWH-007, or 1-pentyl-2-methyl-3-(1-naphthoyl)indole;
      - (ii) JWH-015, or 1-propyl-2-methyl-3-(1-naphthoyl)indole;
      - (iii) JWH-018, or 1-pentyl-3-(1-naphthoyl)indole;
      - (iv) JWH-019, or 1-hexyl-3-(1-naphthoyl)indole;
      - (v) JWH-073, or 1-butyl-3-(1-naphthoyl)indole;
      - (vi) JWH-081, or 1-pentyl-3-(4-methoxy-1-naphthoyl)indole;
      - (vii) JWH-098, or 1-pentyl-2-methyl-3-(4-methoxy-1-naphthoyl)indole;
      - (viii) JWH-122, or 1-pentyl-3-(4-methyl-1-naphthoyl)indole;
      - (ix) JWH-164, or 1-pentyl-3-(7-methoxy-1-naphthoyl)indole;
      - (x) JWH-200, or 1-(2-(4-(morpholinyl)ethyl))-3-(1-naphthoyl)indole;
      - (xi) JWH-210, or 1-pentyl-3-(4-ethyl-1-naphthoyl)indole;
      - (xii) JWH-398, or 1-pentyl-3-(4-chloro-1-naphthoyl)indole;
    - b. Any compound structurally derived from 3-(1-naphthoyl)pyrrole by substitution at the nitrogen atom of the pyrrole ring by alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the pyrrole ring to any extent, whether or not substituted in the naphthyl ring to any extent;
    - c. Any compound structurally derived from 1-(1-naphthylmethyl)indene by substitution at the 3-position of the indene ring by alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indene ring to any extent, whether or not substituted in the naphthyl ring to any extent;
    - d. Any compound structurally derived from 3-phenylacetylindole by substitution at the nitrogen atom of the indole ring with alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent, whether or not substituted in the phenyl ring to any extent. Including, but not limited to:

- (i) JWH-201, or 1-pentyl-3-(4-methoxyphenylacetyl)indole;
- (ii) JWH-203, or 1-pentyl-3-(2-chlorophenylacetyl)indole;
- (iii) JWH-250, or 1-pentyl-3-(2-methoxyphenylacetyl)indole;
- (iv) JWH-251, or 1-pentyl-3-(2-methylphenylacetyl)indole;
- (v) RCS-8, or 1-(2-cyclohexylethyl)-3-(2-methoxyphenylacetyl)indole;

e. Any compound structurally derived from 2-(3-hydroxycyclohexyl)phenol by substitution at the 5-position of the phenolic ring by alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidiny)methyl or 2-(4-morpholinyl)ethyl group, whether or not substituted in the cyclohexyl ring to any extent. Including, but not limited to:

(i) CP 47, 497 & homologues, or 2- $\alpha$ -(1R,3S)-3-hydroxycyclohexyl-5-(2-methyloctan-2-yl)phenol), where side chain n=5, and homologues where side chain n=4,6, or 7;

f. Any compound containing a 3-(benzoyl)indole structure with substitution at the nitrogen atom of the indole ring by alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidiny)methyl or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent. Including, but not limited to:

(i) AM-694, or 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole;

(ii) RCS-4, or 1-pentyl-3-(4-methoxybenzoyl)indole;

g. CP 50,556-1, or  $\alpha$ -(6S,6aR,9R,10aR)-9-hydroxy-6-methyl-3- $\alpha$ -(2R)-5-phenylpentan-2-yl- $\alpha$ -oxy-5,6,6a,7,8,9,10,10a-octahydrophenanthridin-1-yl acetate;

h. HU-210, or (6aR,10aR)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[*a*]chromen-1-ol;

i. HU-211, or Dexanabinol, (6aS,10aS)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[*a*]chromen-1-ol;

j. CP 50,556-1, or  $\alpha$ -(6S,6aR,9R,10aR)-9-hydroxy-6-methyl-3- $\alpha$ -(2R)-5-phenylpentan-2-yl- $\alpha$ -oxy-5,6,6a,7,8,9,10,10a-octahydrophenanthridin-1-yl acetate;

k. Dimethylheptylpyran, or DMHP;

(5) Any material, compound, mixture or preparation containing any quantity of the following substances having a depressant effect on the central nervous system, including their salts, isomers and salts of isomers whenever the existence of these salts, isomers and salts of isomers is possible within the specific chemical designation:

- (a) Gamma-hydroxybutyric acid;
- (b) Mecloqualone;
- (c) Methaqualone;

(6) Any material, compound, mixture or preparation containing any quantity of the following substances having a stimulant effect on the central nervous system, including their salts, isomers and salts of isomers:

- (a) Aminorex;
- (b) N-benzylpiperazine;
- (c) Cathinone;
- (d) Fenethylamine;
- (e) 3-Fluoromethcathinone;
- (f) 4-Fluoromethcathinone;
- (g) Mephedrone, or 4-methylmethcathinone;
- (h) Methcathinone;
- (i) 4-methoxymethcathinone;
- (j) (+, -)cis-4-methylaminorex ((+,-)cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazoline);
- (k) Methylenedioxypyrovalerone, MDPV, or (1-(1,3-Benzodioxol-5-yl)-2-(1-pyrrolidinyl)-1-pentanone);
- (l) Methylone, or 3,4-Methylenedioxymethcathinone;
- (m) 4-Methyl-alpha-pyrrolidinobutylphenone, or MPBP;
- (n) N-ethylamphetamine;
- (o) N,N-dimethylamphetamine;

(7) A temporary listing of substances subject to emergency scheduling under federal law shall include any material, compound, mixture or preparation which contains any quantity of the following substances:

- (a) N-(1-benzyl-4-piperidyl)-N-phenylpropanamide (benzylfentanyl), its optical isomers, salts and salts of isomers;
- (b) N-(1-(2-thienyl)methyl-4-piperidyl)-N-phenylpropanamide (thienylfentanyl), its optical isomers, salts and salts of isomers;

(8) Khat, to include all parts of the plant presently classified botanically as *catha edulis*, whether growing or not; the seeds thereof; any extract from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seed or extracts.

3. The department of health and senior services shall place a substance in Schedule II if it finds that:

- (1) The substance has high potential for abuse;
- (2) The substance has currently accepted medical use in treatment in the United States, or currently accepted medical use with severe restrictions; and
- (3) The abuse of the substance may lead to severe psychic or physical dependence.

4. The controlled substances listed in this subsection are included in Schedule II:

(1) Any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis:

(a) Opium and opiate and any salt, compound, derivative or preparation of opium or opiate, excluding apomorphine, thebaine-derived butorphanol, dextrophan, nalbuphine, nalmeferene, naloxone and naltrexone, and their respective salts but including the following:

- a. Raw opium;
- b. Opium extracts;
- c. Opium fluid;
- d. Powdered opium;
- e. Granulated opium;
- f. Tincture of opium;
- g. Codeine;
- h. Ethylmorphine;
- i. Etorphine hydrochloride;
- j. Hydrocodone;
- k. Hydromorphone;
- l. Metopon;
- m. Morphine;
- n. Oxycodone;
- o. Oxymorphone;
- p. Thebaine;

(b) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in this subdivision, but not including the isoquinoline alkaloids of opium;

(c) Opium poppy and poppy straw;

(d) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extractions which do not contain cocaine or ecgonine;

(e) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid or powder form which contains the phenanthrene alkaloids of the opium poppy);

(2) Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation, dextrophan and levopropoxyphene excepted:

- (a) Alfentanil;
- (b) Alphaprodine;
- (c) Anileridine;
- (d) Bezitramide;
- (e) Bulk dextropropoxyphene;
- (f) Carfentanil;
- (g) Dihydrocodeine;
- (h) Diphenoxylate;
- (i) Fentanyl;
- (j) Isomethadone;
- (k) Levo-alpha-acetylmethadol;
- (l) Levomethorphan;

- (m) Levorphanol;
  - (n) Metazocine;
  - (o) Methadone;
  - (p) Meperidine;
  - (q) Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenylbutane;
  - (r) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane--carboxylic acid;
  - (s) Pethidine (meperidine);
  - (t) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine;
  - (u) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate;
  - (v) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid;
  - (w) Phenazocine;
  - (x) Piminodine;
  - (y) Racemethorphan;
  - (z) Racemorphan;
  - (aa) Remifentanil;
  - (bb) Sufentanil;
  - (cc) Tapentadol;
- (3) Any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:
- (a) Amphetamine, its salts, optical isomers, and salts of its optical isomers;
  - (b) Lisdexamphetamine, its salts, isomers, and salts of its isomers;
  - (c) Methamphetamine, its salts, isomers, and salts of its isomers;
  - (d) Phenmetrazine and its salts;
  - (e) Methylphenidate;
- (4) Any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation:
- (a) Amobarbital;
  - (b) Glutethimide;
  - (c) Pentobarbital;
  - (d) Phencyclidine;
  - (e) Secobarbital;
- (5) Any material or compound which contains any quantity of nabilone;
- (6) Any material, compound, mixture, or preparation which contains any quantity of the following substances:
- (a) Immediate precursor to amphetamine and methamphetamine: Phenylacetone;
  - (b) Immediate precursors to phencyclidine (PCP):
    - a. 1-phenylcyclohexylamine;
    - b. 1-piperidinocyclohexanecarbonitrile (PCC);
- (7) Any material, compound, mixture, or preparation which contains any quantity of the following alkyl nitrites:
- (a) Amyl nitrite;
  - (b) Butyl nitrite.
5. The department of health and senior services shall place a substance in Schedule III if it finds that:
- (1) The substance has a potential for abuse less than the substances listed in Schedules I and II;
  - (2) The substance has currently accepted medical use in treatment in the United States; and
  - (3) Abuse of the substance may lead to moderate or low physical dependence or high psychological dependence.
6. The controlled substances listed in this subsection are included in Schedule III:
- (1) Any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a stimulant effect on the central nervous system:
    - (a) Benzphetamine;
    - (b) Chlorphentermine;
    - (c) Clortermine;
    - (d) Phendimetrazine;
  - (2) Any material, compound, mixture or preparation which contains any quantity or salt of the following substances or salts having a depressant effect on the central nervous system:
    - (a) Any material, compound, mixture or preparation which contains any quantity or salt of the following substances combined with one or more active medicinal ingredients:

- a. Amobarbital;
- b. Secobarbital;
- c. Pentobarbital;
- (b) Any suppository dosage form containing any quantity or salt of the following:
  - a. Amobarbital;
  - b. Secobarbital;
  - c. Pentobarbital;
- (c) Any substance which contains any quantity of a derivative of barbituric acid or its salt;
- (d) Chlorhexadol;
- (e) Embutramide;
- (f) Gamma hydroxybutyric acid and its salts, isomers, and salts of isomers contained in a drug product for which an application has been approved under Section 505 of the federal Food, Drug, and Cosmetic Act;
- (g) Ketamine, its salts, isomers, and salts of isomers;
- (h) Lysergic acid;
- (i) Lysergic acid amide;
- (j) Methypylon;
- (k) Sulfondiethylmethane;
- (l) Sulfonethylmethane;
- (m) Sulfonmethane;
- (n) Tiletamine and zolazepam or any salt thereof;
- (3) Nalorphine;
- (4) Any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs or their salts:
  - (a) Not more than 1.8 grams of codeine per one hundred milliliters or not more than ninety milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium;
  - (b) Not more than 1.8 grams of codeine per one hundred milliliters or not more than ninety milligrams per dosage unit with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;
  - (c) Not more than three hundred milligrams of hydrocodone per one hundred milliliters or not more than fifteen milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium;
  - (d) Not more than three hundred milligrams of hydrocodone per one hundred milliliters or not more than fifteen milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts;
  - (e) Not more than 1.8 grams of dihydrocodeine per one hundred milliliters or not more than ninety milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts;
  - (f) Not more than three hundred milligrams of ethylmorphine per one hundred milliliters or not more than fifteen milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;
  - (g) Not more than five hundred milligrams of opium per one hundred milliliters or per one hundred grams or not more than twenty-five milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts;
  - (h) Not more than fifty milligrams of morphine per one hundred milliliters or per one hundred grams, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;
- (5) Any material, compound, mixture, or preparation containing any of the following narcotic drugs or their salts, as set forth in subdivision (6) of this subsection; buprenorphine;
- (6) Anabolic steroids. Any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone) that promotes muscle growth, except an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the Secretary of Health and Human Services for that administration. If any person prescribes, dispenses, or distributes such steroid for human use, such person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of this subdivision. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation containing any quantity of the following substances, including its salts, esters and ethers:
  - (a) 3{,17-dihydroxy-5a-androstane;
  - (b) 3@,17{-dihydroxy-5a-androstane;
  - (c) 5@-androstane-3,17-dione;
  - (d) 1-androstenediol (3{,17{-dihydroxy-5@-androst-1-ene);
  - (e) 1-androstenediol (3@,17{-dihydroxy-5@-androst-1-ene);
  - (f) 4-androstenediol (3{,17{-dihydroxy-androst-4-ene);

(g) 5-androstenediol (3{,17{-dihydroxy-androst-5-ene);  
 (h) 1-androstenedione (â5@â-androst-1-en-3,17-dione);  
 (i) 4-androstenedione (androst-4-en-3,17-dione);  
 (j) 5-androstenedione (androst-5-en-3,17-dione);  
 (k) Bolasterone (7@, 17@-dimethyl-17{-hydroxyandrost-4-en-3-one);  
 (l) Boldenone (17{-hydroxyandrost-1,4,-diene-3-one);  
 (m) Boldione;  
 (n) Calusterone (7{, 17@-dimethyl-17{-hydroxyandrost-4-en-3-one);  
 (o) Clostebol (4-chloro-17{-hydroxyandrost-4-en-3-one);  
 (p) Dehydrochloromethyltestosterone (4-chloro-17{-hydroxy-17@-methyl-androst-1,4-dien-3-one);  
 (q) Desoxymethyltestosterone;  
 (r) }1-dihydrotestosterone (a.k.a. '1-testosterone')(17{-hydroxy-5@-androst-1-en-3-one);  
 (s) 4-dihydrotestosterone (17{-hydroxy-androstan-3-one);  
 (t) Drostanolone (17{-hydroxy-2@-methyl-5@-androstan-3-one);  
 (u) Ethylestrenol (17@-ethyl-17{-hydroxyestr-4-ene);  
 (v) Fluoxymesterone (9-fluoro-17@-methyl-11{,17{-dihydroxyandrost-4-en-3-one);  
 (w) Formebolone (2-formyl-17@-methyl-11@,17{-dihydroxyandrost-1,4-dien-3-one);  
 (x) Furazabol (17@-methyl-17{-hydroxyandrostanô2,3-câ-furazan);  
 (y) 13{-ethyl-17{-hydroxygon-4-en-3-one);  
 (z) 4-hydroxytestosterone (4,17{-dihydroxy-androst-4-en-3-one);  
  
 (aa) 4-hydroxy-19-nortestosterone (4,17{-dihydroxy-estr-4-en-3-one);  
 (bb) Mestanolone (17@-methyl-17{-hydroxy-5-androstan-3-one);  
 (cc) Mesterolone (1@methyl-17{-hydroxy-â5@â-androstan-3-one);  
 (dd) Methandienone (17@-methyl-17{-hydroxyandrost-1,4-dien-3-one);  
 (ee) Methandiol (17@-methyl-3{,17{-dihydroxyandrost-5-ene);  
 (ff) Methenolone (1-methyl-17{-hydroxy-5@-androst-1-en-3-one);  
 (gg) 17@-methyl-3{,17{-dihydroxy-5a-androstane);  
 (hh) 17@-methyl-3@,17{-dihydroxy-5a-androstane);  
 (ii) 17@-methyl-3{,17{-dihydroxyandrost-4-ene);  
 (jj) 17@-methyl-4-hydroxynandrolone (17@-methyl-4-hydroxy-17{-hydroxyestr-4-en-3-one);  
 (kk) Methyldienolone (17@-methyl-17{-hydroxyestra-4,9(10)-dien-3-one);  
 (ll) Methyltrienolone (17@-methyl-17{-hydroxyestra-4,9-11-trien-3-one);  
 (mm) Methyltestosterone (17@-methyl-17{-hydroxyandrost-4-en-3-one);  
 (nn) Mibolerone (7@,17@-dimethyl-17{-hydroxyestr-4-en-3-one);  
 (oo) 17@-methyl-}1-dihydrotestosterone (17b{-hydroxy-17@-methyl-5@-androst-1-en-3-one)(a.k.a. '17-@-methyl-1-testosterone');  
 (pp) Nandrolone (17{-hydroxyestr-4-ene-3-one);  
 (qq) 19-nor-4-androstenediol (3{,17{-dihydroxyestr-4-ene);  
 (rr) 19-nor-4-androstenediol (3@,17{-dihydroxyestr-4-ene);  
 (ss) 19-nor-4,9(10)-androstadienedione;  
 (tt) 19-nor-5-androstenediol (3{,17{-dihydroxyestr-5-ene);  
 (uu) 19-nor-5-androstenediol (3@,17{-dihydroxyestr-5-ene);  
 (vv) 19-nor-4-androstenedione (estr-4-en-3,17-dione);  
 (ww) 19-nor-5-androstenedione (estr-5-en-3,17-dione);  
 (xx) Norbolethone (13{,17@-diethyl-17{-hydroxygon-4-en-3-one);  
 (yy) Norclostebol (4-chloro-17{-hydroxyestr-4-en-3-one);  
 (zz) Norethandrolone (17@-ethyl-17{-hydroxyestr-4-en-3-one);  
 (aaa) Normethandrolone (17@-methyl-17{-hydroxyestr-4-en-3-one);  
 (bbb) Oxandrolone (17@-methyl-17{-hydroxy-2-oxa-â5@â-androstan-3-one);  
 (ccc) Oxymesterone (17@-methyl-4,17{-dihydroxyandrost-4-en-3-one);  
 (ddd) Oxymethalone (17a-methyl-2-hydroxymethylene-17{-hydroxy-â5@â-androstan-3-one);  
 (eee) Stanozolol (17@-methyl-17{-hydroxy-â5@â-androst-2-enoâ3,2-câ-pyrazole);  
 (fff) Stenbolone (17{-hydroxy-2-methyl-â5@â-androst-1-en-3-one);  
 (ggg) Testolactone (13-hydroxy-3-oxo-13,17-secoandrosta-1,4-dien-17-oic acid lactone);  
 (hhh) Testosterone (17{-hydroxyandrost-4-en-3-one);



(iii) Tetrahydrogestrinone (13 $\beta$ ,17 $\alpha$ -diethyl-17 $\beta$ -hydroxygon-4,9,11-trien-3-one);

(jjj) Trenbolone (17 $\beta$ -hydroxyestr-4,9,11-trien-3-one);

(kkk) Any salt, ester, or ether of a drug or substance described or listed in this subdivision, except an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the Secretary of Health and Human Services for that administration;

(7) Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a United States Food and Drug Administration approved drug product;

(8) The department of health and senior services may except by rule any compound, mixture, or preparation containing any stimulant or depressant substance listed in subdivisions (1) and (2) of this subsection from the application of all or any part of sections 195.010 to 195.320 if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a stimulant or depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of the substances which have a stimulant or depressant effect on the central nervous system.

7. The department of health and senior services shall place a substance in Schedule IV if it finds that:

(1) The substance has a low potential for abuse relative to substances in Schedule III;

(2) The substance has currently accepted medical use in treatment in the United States; and

(3) Abuse of the substance may lead to limited physical dependence or psychological dependence relative to the substances in Schedule III.

8. The controlled substances listed in this subsection are included in Schedule IV:

(1) Any material, compound, mixture, or preparation containing any of the following narcotic drugs or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

(a) Not more than one milligram of difenoxin and not less than twenty-five micrograms of atropine sulfate per dosage unit;

(b) Dextropropoxyphene (alpha-(+)-4-dimethylamino-1, 2-diphenyl-3-methyl-2-propionoxybutane);

(c) Any of the following limited quantities of narcotic drugs or their salts, which shall include one or more non-narcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

a. Not more than two hundred milligrams of codeine per one hundred milliliters or per one hundred grams;

b. Not more than one hundred milligrams of dihydrocodeine per one hundred milliliters or per one hundred grams;

c. Not more than one hundred milligrams of ethylmorphine per one hundred milliliters or per one hundred grams;

(2) Any material, compound, mixture or preparation containing any quantity of the following substances, including their salts, isomers, and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation:

(a) Alprazolam;

(b) Barbitol;

(c) Bromazepam;

(d) Camazepam;

(e) Chloral betaine;

(f) Chloral hydrate;

(g) Chlordiazepoxide;

(h) Clobazam;

(i) Clonazepam;

(j) Clorazepate;

(k) Clotiazepam;

(l) Cloxazolam;

(m) Delorazepam;

(n) Diazepam;

(o) Dichloralphenazone;

(p) Estazolam;

(q) Ethchlorvynol;

(r) Ethinamate;

(s) Ethyl loflazepate;

(t) Fludiazepam;

(u) Flunitrazepam;

- (v) Flurazepam;
- (w) Fospropofol;
- (x) Halazepam;
- (y) Haloxazolam;
- (z) Ketazolam;
- (aa) Loprazolam;
- (bb) Lorazepam;
- (cc) Lormetazepam;
- (dd) Mebutamate;
- (ee) Medazepam;
- (ff) Meprobamate;
- (gg) Methohexital;
- (hh) Methylphenobarbital (mephobarbital);
- (ii) Midazolam;
- (jj) Nimetazepam;
- (kk) Nitrazepam;
- (ll) Nordiazepam;
- (mm) Oxazepam;
- (nn) Oxazolam;
- (oo) Paraldehyde;
- (pp) Petrichloral;
- (qq) Phenobarbital;
- (rr) Pinazepam;
- (ss) Prazepam;
- (tt) Quazepam;
- (uu) Temazepam;
- (vv) Tetrazepam;
- (ww) Triazolam;
- (xx) Zaleplon;
- (yy) Zolpidem;
- (zz) Zopiclone;

(3) Any material, compound, mixture, or preparation which contains any quantity of the following substance including its salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible: fenfluramine;

(4) Any material, compound, mixture or preparation containing any quantity of the following substances having a stimulant effect on the central nervous system, including their salts, isomers and salts of isomers:

- (a) Cathine ((+)-norpseudoephedrine);
- (b) Diethylpropion;
- (c) Fencamfamin;
- (d) Fenproporex;
- (e) Mazindol;
- (f) Mefenorex;
- (g) Modafinil;
- (h) Pemoline, including organometallic complexes and chelates thereof;
- (i) Phentermine;
- (j) Pipradrol;
- (k) Sibutramine;
- (l) SPA ((-)-1-dimethylamino-1,2-diphenylethane);

(5) Any material, compound, mixture or preparation containing any quantity of the following substance, including its salts:

- (a) butorphanol;
- (b) pentazocine;

(6) Ephedrine, its salts, optical isomers and salts of optical isomers, when the substance is the only active medicinal ingredient;

(7) The department of health and senior services may except by rule any compound, mixture, or preparation containing any depressant substance listed in subdivision (1) of this subsection from the application of all or any part of sections 195.010 to 195.320 if the compound, mixture, or preparation contains one or more active medicinal ingre-

dients not having a depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of the substances which have a depressant effect on the central nervous system.

9. The department of health and senior services shall place a substance in Schedule V if it finds that:

- (1) The substance has low potential for abuse relative to the controlled substances listed in Schedule IV;
- (2) The substance has currently accepted medical use in treatment in the United States; and
- (3) The substance has limited physical dependence or psychological dependence liability relative to the controlled substances listed in Schedule IV.

10. The controlled substances listed in this subsection are included in Schedule V:

(1) Any compound, mixture or preparation containing any of the following narcotic drugs or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below, which also contains one or more non-narcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

(a) Not more than two and five-tenths milligrams of diphenoxylate and not less than twenty-five micrograms of atropine sulfate per dosage unit;

(b) Not more than one hundred milligrams of opium per one hundred milliliters or per one hundred grams;

(c) Not more than five-tenths milligram of difenoxin and not less than twenty-five micrograms of atropine sulfate per dosage unit;

(2) Any material, compound, mixture or preparation which contains any quantity of the following substance having a stimulant effect on the central nervous system including its salts, isomers and salts of isomers: pyrovalerone;

(3) Any compound, mixture, or preparation containing any detectable quantity of pseudoephedrine or its salts or optical isomers, or salts of optical isomers or any compound, mixture, or preparation containing any detectable quantity of ephedrine or its salts or optical isomers, or salts of optical isomers;

(4) Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts:

(a) Lacosamide;

(b) Pregabalin.

11. If any compound, mixture, or preparation as specified in subdivision (3) of subsection 10 of this section is dispensed, sold, or distributed in a pharmacy without a prescription:

(1) All packages of any compound, mixture, or preparation containing any detectable quantity of pseudoephedrine, its salts or optical isomers, or salts of optical isomers or ephedrine, its salts or optical isomers, or salts of optical isomers, shall be offered for sale only from behind a pharmacy counter where the public is not permitted, and only by a registered pharmacist or registered pharmacy technician; and

(2) Any person purchasing, receiving or otherwise acquiring any compound, mixture, or preparation containing any detectable quantity of pseudoephedrine, its salts or optical isomers, or salts of optical isomers or ephedrine, its salts or optical isomers, or salts of optical isomers shall be at least eighteen years of age; and

(3) The pharmacist, intern pharmacist, or registered pharmacy technician shall require any person, prior to their purchasing, receiving or otherwise acquiring such compound, mixture, or preparation to furnish suitable photo identification that is issued by a state or the federal government or a document that, with respect to identification, is considered acceptable and showing the date of birth of the person;

(4) The seller shall deliver the product directly into the custody of the purchaser.

12. Pharmacists, intern pharmacists, and registered pharmacy technicians shall implement and maintain an electronic log of each transaction. Such log shall include the following information:

(1) The name, address, and signature of the purchaser;

(2) The amount of the compound, mixture, or preparation purchased;

(3) The date and time of each purchase; and

(4) The name or initials of the pharmacist, intern pharmacist, or registered pharmacy technician who dispensed the compound, mixture, or preparation to the purchaser.

13. Each pharmacy shall submit information regarding sales of any compound, mixture, or preparation as specified in subdivision (3) of subsection 10 of this section in accordance with transmission methods and frequency established by the department by regulation;

14. No person shall dispense, sell, purchase, receive, or otherwise acquire quantities greater than those specified in this chapter.

15. All persons who dispense or offer for sale pseudoephedrine and ephedrine products in a pharmacy shall ensure that all such products are located only behind a pharmacy counter where the public is not permitted.

16. Any person who knowingly or recklessly violates the provisions of subsections 11 to 15 of this section is guilty of a class A misdemeanor.

17. The scheduling of substances specified in subdivision (3) of subsection 10 of this section and subsections 11, 12, 14, and 15 of this section shall not apply to any compounds, mixtures, or preparations that are in liquid or liquid-filled gel capsule form or to any compound, mixture, or preparation specified in subdivision (3) of subsection 10 of this section which must be dispensed, sold, or distributed in a pharmacy pursuant to a prescription.

18. The manufacturer of a drug product or another interested party may apply with the department of health and senior services for an exemption from this section. The department of health and senior services may grant an exemption by rule from this section if the department finds the drug product is not used in the illegal manufacture of methamphetamine or other controlled or dangerous substances. The department of health and senior services shall rely on reports from law enforcement and law enforcement evidentiary laboratories in determining if the proposed product can be used to manufacture illicit controlled substances.

19. The department of health and senior services shall revise and republish the schedules annually.

20. The department of health and senior services shall promulgate rules under chapter 536 regarding the security and storage of Schedule V controlled substances, as described in subdivision (3) of subsection 10 of this section, for distributors as registered by the department of health and senior services.

21. Logs of transactions required to be kept and maintained by this section and section 195.417 shall create a rebuttable presumption that the person whose name appears in the logs is the person whose transactions are recorded in the logs.

*(L. 1971 H.B. 69, A.L. 1987 H.B. 51 & 49, A.L. 1989 S.B. 215 & 58, A.L. 1994 S.B. 594, A.L. 1996 H.B. 1301 & 1298, A.L. 1997 H.B. 635, A.L. 1998 H.B. 1357, A.L. 2001 H.B. 471, A.L. 2005 H.B. 353 merged with H.B. 441 merged with S.B. 10 & 27, A.L. 2006 S.B. 756, A.L. 2008 S.B. 724, A.L. 2010 H.B. 1472, A.L. 2011 H.B. 641)*

**195.030. Rules, procedure--fees--registration required, exceptions, registration, term not to exceed three years.**

1. The department of health and senior services upon public notice and hearing pursuant to this section and chapter 536, RSMo, may promulgate rules and charge reasonable fees relating to the registration and control of the manufacture, distribution and dispensing of controlled substances within this state. No rule or portion of a rule promulgated pursuant to the authority of this chapter shall become effective unless it has been promulgated pursuant to the provisions of section 536.024, RSMo.

2. No person shall manufacture, compound, mix, cultivate, grow, or by any other process produce or prepare, distribute, dispense or prescribe any controlled substance and no person as a wholesaler shall supply the same, without having first obtained a registration issued by the department of health and senior services in accordance with rules and regulations promulgated by it. No registration shall be granted for a term exceeding three years.

3. Persons registered by the department of health and senior services pursuant to sections 195.005 to 195.425 to manufacture, distribute, or dispense or conduct research with controlled substances are authorized to possess, manufacture, distribute or dispense such substances, including any such activity in the conduct of research, to the extent authorized by their registration and in conformity with other provisions of sections 195.005 to 195.425.

4. The following persons shall not be required to register and may lawfully possess controlled substances pursuant to sections 195.005 to 195.425:

(1) An agent or employee, excluding physicians, dentists, optometrists, podiatrists or veterinarians, of any registered manufacturer, distributor, or dispenser of any controlled substance if such agent is acting in the usual course

of his or her business or employment;

(2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of any controlled substance is in the usual course of business or employment;

(3) An ultimate user or a person in possession of any controlled substance pursuant to a lawful order of a practitioner or in lawful possession of a Schedule V substance.

5. The department of health and senior services may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if it finds it consistent with the public health and safety.

6. A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances.

7. The department of health and senior services is authorized to inspect the establishment of a registrant or applicant in accordance with the provisions of sections 195.005 to 195.425.

*(RSMo 1939 § 9834, A.L. 1971 H.B. 69, A.L. 1989 S.B. 215 & 58, A.L. 1993 S.B. 52, A.L. 1995 S.B. 3, A.L. 1997 H.B. 635, A.L. 1999 H.B. 94 merged with S.B. 216)*

**195.040. Registration requirements--revocation and suspension--review by administrative hearing commission--reapplication may be denied up to five years.**

1. No registration shall be issued under section 195.030 unless and until the applicant therefor has furnished proof satisfactory to the department of health and senior services:

(1) That the applicant is of good moral character or, if the applicant be an association or corporation, that the managing officers are of good moral character;

(2) That the applicant is equipped as to land, buildings, and paraphernalia properly to carry on the business described in his application.

2. No registration shall be granted to any person who has within two years been finally adjudicated and found guilty, or entered a plea of guilty or nolo contendere, in a criminal prosecution under the laws of any state or of the United States, for any misdemeanor offense or within seven years for any felony offense related to controlled substances. No registration shall be granted to any person who is abusing controlled substances.

3. The department of health and senior services shall register an applicant to manufacture, distribute or dispense controlled substances unless it determines that the issuance of that registration would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) Maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels;

(2) Compliance with applicable state and local law;

(3) Any convictions of an applicant under any federal or state laws relating to any controlled substance;

(4) Past experience in the manufacture or distribution of controlled substances and the existence in the applicant's establishment of effective controls against diversion;

(5) Furnishing by the applicant of false or fraudulent material information in any application filed under sections 195.005 to 195.425;

(6) Suspension or revocation of the applicant's federal registration to manufacture, distribute or dispense narcotics or controlled dangerous drugs as authorized by federal law; and

(7) Any other factors relevant to and consistent with the public health and safety.

4. Registration does not entitle a registrant to manufacture and distribute controlled substances in Schedule I or II other than those specified in the registration.

5. Practitioners shall be registered to dispense any controlled substance or to conduct research with controlled substances in Schedules II through V if they are authorized to dispense or conduct research under the laws of this state. The department of health and senior services need not require separate registration under sections 195.005 to 195.425 for practitioners engaging in research with nonnarcotic substances in Schedules II through V where the registrant is already registered under sections 195.005 to 195.425 in another capacity. Practitioners registered under federal law to conduct research with Schedule I substances may conduct research with Schedule I substances within this state upon furnishing the department of health and senior services evidence of that federal registration.

6. Compliance by manufacturers and distributors with the provisions of federal law respecting registration (excluding fees) shall entitle them to be registered under sections 195.005 to 195.425.

7. A registration to manufacture, distribute, or dispense a controlled substance may be suspended or revoked by the department of health and senior services upon a finding that the registrant:

- (1) Has furnished false or fraudulent material information in any application filed under sections 195.005 to 195.425;
- (2) Has been convicted of a felony under any state or federal law relating to any controlled substance;
- (3) Has had his federal registration to manufacture, distribute or dispense suspended or revoked;
- (4) Has violated any federal controlled substances statute or regulation, or any provision of sections 195.005 to 195.425 or regulation promulgated pursuant to sections 195.005 to 195.425; or
- (5) Has had the registrant's professional license to practice suspended or revoked.

8. The department of health and senior services may warn or censure a registrant; limit a registration to particular controlled substances or schedules of controlled substances; limit revocation or suspension of a registration to a particular controlled substance with respect to which grounds for revocation or suspension exist; restrict or limit a registration under such terms and conditions as the department of health and senior services considers appropriate for a period of five years; suspend or revoke a registration for a period not to exceed five years; or deny an application for registration. In any order of revocation, the department of health and senior services may provide that the registrant may not apply for a new registration for a period of time ranging from one to five years following the date of the order of revocation. All stay orders shall toll this time period. Any registration placed under a limitation or restriction by the department of health and senior services shall be termed "under probation".

9. If the department of health and senior services suspends or revokes a registration, all controlled substances owned or possessed by the registrant at the time of suspension or the effective date of the revocation order may be placed under seal by such agency and held pending final disposition of the case. No disposition may be made of substances under seal until the time for taking an appeal has elapsed or until all appeals have been concluded, unless a court, upon application therefor, orders the sale of perishable substances and the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all controlled substances may be forfeited to the state.

10. The department of health and senior services may, upon review, terminate any restriction or limitation previously imposed upon a registration by the department of health and senior services if the registrant has remained in compliance with the imposed restrictions or limitations and local, state and federal laws since the time the restrictions\* or limitations were imposed.

11. The department of health and senior services shall promptly notify the Drug Enforcement Administration, United States Department of Justice, or its successor agency, of all orders suspending or revoking registration and all forfeitures of controlled substances.

12. If after first providing the registrant an opportunity for an informal conference, the department of health and senior services proposes to deny, suspend, restrict, limit or revoke a registration or refuse a renewal of registration, the department of health and senior services shall serve upon the applicant or registrant written notice of the proposed action to be taken on the application or registration. The notice shall contain a statement of the type of discipline proposed, the basis therefor, the date such action shall go into effect and a statement that the registrant shall have thirty days to request in writing a hearing before the administrative hearing commission. If no written request for a hearing is received by the department of health and senior services within thirty days of the applicant's or registrant's receipt of the notice, the proposed discipline shall take effect thirty-one days from the date the original notice was received by the applicant or registrant. If the registrant or applicant makes a written request for a hearing, the department of health and senior services shall file a complaint with the administrative hearing commission within sixty days of receipt of the written request for a hearing. The complaint shall comply with the laws and regulations for actions brought before the administrative hearing commission. The department of health and senior services may issue letters of censure or warning and may enter into agreements with a registrant or applicant which restrict or limit a registration without formal notice or hearing.

13. The department of health and senior services may suspend any registration simultaneously with the institution of proceedings under subsection 7 of this section if the department of health and senior services finds that there is imminent danger to the public health or safety which warrants this action. The suspension shall continue in effect

until the conclusion of the proceedings, including review thereof, unless sooner withdrawn by the department of health and senior services, dissolved by a court of competent jurisdiction or stayed by the administrative hearing commission.

(RSMo 1939 § 9835, A.L. 1971 H.B. 69, A.L. 1978 S.B. 651, A.L. 1987 H.B. 51 & 49, A.L. 1989 S.B. 215 & 58, A.L. 1994 S.B. 594, A.L. 1997 H.B. 635, A.L. 1998 H.B. 1147, et al.)

*\*Word "restriction" appears in original rolls.*

**195.041. Emergencies, waiver of registration and record-keeping requirements for controlled substances, when.**

In the event of an emergency as defined in section 44.010, RSMo, the department of health and senior services may waive the registration and record-keeping requirements set forth in sections 195.010 to 195.100 and their attendant regulations if the department determines such a waiver would be in the best interest of the public health.

(L. 2002 S.B. 712)

**195.042. Confidentiality of all complaints, investigatory reports and information, exceptions.**

All complaints, investigatory reports, and information pertaining to any applicant, registrant or individual are confidential and shall only be disclosed upon written consent of the person whose records are involved or to other administrative or law enforcement agencies acting within the scope of their statutory authority. However, no applicant, registrant or individual shall have access to any complaints, investigatory reports or information concerning an investigation in progress until such time as the investigation has been completed. Information regarding identity, including names and addresses, registration, final disciplinary action taken and currency of the registration of the persons possessing registrations to conduct activities involving controlled substances and the names and addresses of the applicants shall not be confidential. This section shall not be construed to authorize the release of records, reports or other information which may be held in department files for any registrant or applicant which are subject to other specific state or federal laws concerning their disclosure.

(L. 1994 S.B. 594)

**195.045. Civil immunity for persons required to report to the department of health and senior services.**

Any person, organization, association or corporation who reports or provides information to the department of health and senior services pursuant to the provisions of this chapter and who does so in good faith shall not be subject to an action for civil damages as a result thereof.

(L. 1997 H.B. 635)

**195.050. Controlled substances, legal sales, how made--records required to be kept.**

1. A duly registered manufacturer or wholesaler may sell controlled substances to any of the following persons:

- (1) To a manufacturer, wholesaler, or pharmacy;
- (2) To a physician, dentist, podiatrist or veterinarian;
- (3) To a person in charge of a hospital, but only for use in that hospital;
- (4) To a person in charge of a laboratory, but only for use in that laboratory for scientific and medical purposes.

2. A duly registered manufacturer or wholesaler may sell controlled substances to any of the following persons:

(1) On a special written order accompanied by a certificate of exemption, as required by federal laws, to a person in the employ of the United States government or of any state, territorial, district, county, municipal or insular government, purchasing, receiving, possessing, or dispensing controlled substances by reason of his official duties;

(2) To a master of a ship or person in charge of any aircraft upon which no physician is regularly employed, for the actual medical needs of persons on board such ship or aircraft, when not in port; provided, such controlled substances shall be sold to the master of such ship or person in charge of such aircraft only in pursuance of a special order form approved by a commissioned medical officer or acting surgeon of the United States Public Health Service;

(3) To a person in a foreign country if the provisions of federal laws are complied with.

3. An official written order for any controlled substance listed in Schedules I and II shall be signed in duplicate by the person giving the order or by his duly authorized agent. The original shall be presented to the person who sells or dispenses the controlled substance named therein. In event of the acceptance of such order by the person, each party to the transaction shall preserve his copy of such order for a period of two years in such a way as to be readily accessible for inspection by any public officer or employee engaged in the enforcement of sections 195.005 to 195.425. It shall be deemed a compliance with this subsection if the parties to the transaction have complied with

federal laws, respecting the requirements governing the use of order forms.

4. Possession of or control of controlled substances obtained as authorized by this section shall be lawful if in the regular course of business, occupation, profession, employment, or duty of the possessor.

5. A person in charge of a hospital or of a laboratory, or in the employ of this state or of any other state, or of any political subdivision thereof, and a master or other proper officer of a ship or aircraft, who obtains controlled substances under the provisions of this section or otherwise, shall not administer, nor dispense, nor otherwise use such drugs, within this state, except within the scope of his employment or official duty, and then only for scientific or medicinal purposes and subject to the provisions of sections 195.005 to 195.425.

6. Every person registered to manufacture, distribute or dispense controlled substances under sections 195.005 to 195.425 shall keep records and inventories of all such drugs in conformance with the record keeping and inventory requirements of federal law, and in accordance with any additional regulations of the department of health and senior services.

7. Manufacturers and wholesalers shall keep records of all narcotic and controlled substances compounded, mixed, cultivated, grown, or by any other process produced or prepared, and of all controlled substances received and disposed of by them, in accordance with this section.

8. Apothecaries shall keep records of all controlled substances received and disposed of by them, in accordance with the provisions of this section.

9. The form of records shall be prescribed by the department of health and senior services.

*(RSMo 1939 § 9836, A.L. 1971 H.B. 69, A.L. 1989 S.B. 215 & 58)*

**195.060. Controlled substances to be dispensed on prescription only, exception.**

1. Except as provided in subsection 3 of this section, a pharmacist, in good faith, may sell and dispense controlled substances to any person only upon a prescription of a practitioner as authorized by statute, provided that the controlled substances listed in Schedule V may be sold without prescription in accordance with regulations of the department of health and senior services. All written prescriptions shall be signed by the person prescribing the same. All prescriptions shall be dated on the day when issued and bearing the full name and address of the patient for whom, or of the owner of the animal for which, the drug is prescribed, and the full name, address, and the registry number under the federal controlled substances laws of the person prescribing, if he is required by those laws to be so registered. If the prescription is for an animal, it shall state the species of the animal for which the drug is prescribed. The person filling the prescription shall either write the date of filling and his own signature on the prescription or retain the date of filling and the identity of the dispenser as electronic prescription information. The prescription or electronic prescription information shall be retained on file by the proprietor of the pharmacy in which it is filled for a period of two years, so as to be readily accessible for inspection by any public officer or employee engaged in the enforcement of this law. No prescription for a drug in Schedule I or II shall be filled more than six months after the date prescribed; no prescription for a drug in schedule I or II shall be refilled; no prescription for a drug in Schedule III or IV shall be filled or refilled more than six months after the date of the original prescription or be refilled more than five times unless renewed by the practitioner.

2. The legal owner of any stock of controlled substances in a pharmacy, upon discontinuance of dealing in such drugs, may sell the stock to a manufacturer, wholesaler, or pharmacist, but only on an official written order.

3. A pharmacist, in good faith, may sell and dispense any Schedule II drug or drugs to any person in emergency situations as defined by rule of the department of health and senior services upon an oral prescription by an authorized practitioner.

4. Except where a bona fide physician-patient-pharmacist relationship exists, prescriptions for narcotics or hallucinogenic drugs shall not be delivered to or for an ultimate user or agent by mail or other common carrier.

*(RSMo 1939 § 9837, A.L. 1957 p. 679, A.L. 1971 H.B. 69, A.L. 1989 S.B. 215 & 58, A.L. 1997 H.B. 635, A.L. 1998 H.B. 1147, et al., A.L. 2005 S.B. 74 & 49, A.L. 2010 H.B. 1965)*



**195.070. Who may prescribe.**

1. A physician, podiatrist, dentist, a registered optometrist certified to administer pharmaceutical agents as provided in section 336.220, RSMo, or a physician assistant in accordance with section 334.747, RSMo, in good faith and in the course of his or her professional practice only, may prescribe, administer, and dispense controlled substances or he or she may cause the same to be administered or dispensed by an individual as authorized by statute.

2. An advanced practice registered nurse, as defined in section 335.016, RSMo, but not a certified registered nurse anesthetist as defined in subdivision (8) of section 335.016, RSMo, who holds a certificate of controlled substance prescriptive authority from the board of nursing under section 335.019, RSMo, and who is delegated the authority to prescribe controlled substances under a collaborative practice arrangement under section 334.104, RSMo, may prescribe any controlled substances listed in Schedules III, IV, and V of section 195.017. However, no such certified advanced practice registered nurse shall prescribe controlled substance for his or her own self or family. Schedule III narcotic controlled substance prescriptions shall be limited to a one hundred twenty-hour supply without refill.

3. A veterinarian, in good faith and in the course of the veterinarian's professional practice only, and not for use by a human being, may prescribe, administer, and dispense controlled substances and the veterinarian may cause them to be administered by an assistant or orderly under his or her direction and supervision.

4. A practitioner shall not accept any portion of a controlled substance unused by a patient, for any reason, if such practitioner did not originally dispense the drug.

5. An individual practitioner shall not prescribe or dispense a controlled substance for such practitioner's personal use except in a medical emergency.

*(RSMo 1939 § 9838, A.L. 1971 H.B. 69, A.L. 1988 H.B. 1242 Revision, A.L. 1993 H.B. 564, A.L. 1997 H.B. 635, A.L. 2001 H.B. 471, A.L. 2008 S.B. 724, A.L. 2009 S.B. 296)*

**195.080. Excepted substances--prescription or dispensing limitation on amount of supply--may be increased by physician, procedure.**

1. Except as otherwise in sections 195.005 to 195.425 specifically provided, sections 195.005 to 195.425 shall not apply to the following cases: prescribing, administering, dispensing or selling at retail of liniments, ointments, and other preparations that are susceptible of external use only and that contain controlled substances in such combinations of drugs as to prevent the drugs from being readily extracted from such liniments, ointments, or preparations, except that sections 195.005 to 195.425 shall apply to all liniments, ointments, and other preparations that contain coca leaves in any quantity or combination.

2. The quantity of Schedule II controlled substances prescribed or dispensed at any one time shall be limited to a thirty-day supply. The quantity of Schedule III, IV or V controlled substances prescribed or dispensed at any one time shall be limited to a ninety-day supply and shall be prescribed and dispensed in compliance with the general provisions of sections 195.005 to 195.425. The supply limitations provided in this subsection may be increased up to three months if the physician describes on the prescription form or indicates via telephone, fax, or electronic communication to the pharmacy to be entered on or attached to the prescription form the medical reason for requiring the larger supply. The supply limitations provided in this subsection shall not apply if the prescription is dispensed directly to a member of the United States armed forces serving outside the United States.

3. The partial filling of a prescription for a Schedule II substance is permissible as defined by regulation by the department of health and senior services.

*(RSMo 1939 § 9839, A.L. 1965 p. 326, A.L. 1971 H.B. 69, A.L. 1987 H.B. 51 & 49, A.L. 1989 S.B. 215 & 58, A.L. 1997 H.B. 635, A.L. 2005 S.B. 74 & 49, A.L. 2010 S.B. 754)*

**195.100. Labeling requirements.**

1. It shall be unlawful to distribute any controlled substance in a commercial container unless such container bears a label containing an identifying symbol for such substance in accordance with federal laws.

2. It shall be unlawful for any manufacturer of any controlled substance to distribute such substance unless the labeling thereof conforms to the requirements of federal law and contains the identifying symbol required in subsection 1 of this section.

3. The label of a controlled substance in Schedule II, III or IV shall, when dispensed to or for a patient, contain a clear, concise warning that it is a criminal offense to transfer such narcotic or dangerous drug to any person other than the patient.

4. Whenever a manufacturer sells or dispenses a controlled substance and whenever a wholesaler sells or dispenses a controlled substance in a package prepared by him or her, the manufacturer or wholesaler shall securely affix to each package in which that drug is contained a label showing in legible English the name and address of the vendor and the quantity, kind, and form of controlled substance contained therein. No person except a pharmacist for the purpose of filling a prescription under sections 195.005 to 195.425, shall alter, deface, or remove any label so affixed.

5. Whenever a pharmacist or practitioner sells or dispenses any controlled substance on a prescription issued by a physician, physician assistant, dentist, podiatrist, veterinarian, or advanced practice registered nurse, the pharmacist or practitioner shall affix to the container in which such drug is sold or dispensed a label showing his or her own name and address of the pharmacy or practitioner for whom he or she is lawfully acting; the name of the patient or, if the patient is an animal, the name of the owner of the animal and the species of the animal; the name of the physician, physician assistant, dentist, podiatrist, advanced practice registered nurse, or veterinarian by whom the prescription was written; the name of the collaborating physician if the prescription is written by an advanced practice registered nurse or the supervising physician if the prescription is written by a physician assistant, and such directions as may be stated on the prescription. No person shall alter, deface, or remove any label so affixed.

*(RSMo 1939 § 9841, A.L. 1971 H.B. 69, A.L. 1989 S.B. 215 & 58, A.L. 1997 H.B. 635, A.L. 1998 H.B. 1147, et al., A.L. 2008 S.B. 724, A.L. 2009 S.B. 296)*

**195.110. User of controlled substance to keep it in container in which obtained.**

A person to whom or for whose use any controlled substance in Schedule II has been prescribed, sold, or dispensed by a physician, dentist, podiatrist, or pharmacist, or other person authorized under the provisions of section 195.050 and the owner of any animal for which any such drug has been prescribed, sold, or dispensed, by a veterinarian, may lawfully possess it only in the container in which it was delivered to him by the person selling or dispensing the same.

*(RSMo 1939 § 9842, A.L. 1971 H.B. 69, A.L. 1997 H.B. 635)*

**195.202. Possession or control of a controlled substance, penalty.**

1. Except as authorized by sections 195.005 to 195.425\*, it is unlawful for any person to possess or have under his control a controlled substance.

2. Any person who violates this section with respect to any controlled substance except thirty-five grams or less of marijuana or any synthetic cannabinoid is guilty of a class C felony.

3. Any person who violates this section with respect to not more than thirty-five grams of marijuana or any synthetic cannabinoid is guilty of a class A misdemeanor.

*(L. 1989 S.B. 215 & 58, A.L. 2010 H.B. 1472, A.L. 2011 H.B. 641)*

*\*Section 195.425 was repealed by H.B. 1965, 2010.*

**195.204. Fraudulently attempting to obtain a controlled substance, penalty.**

1. A person commits the offense of fraudulently attempting to obtain a controlled substance if he obtains or attempts to obtain a controlled substance or procures or attempts to procure the administration of the controlled substance by fraud, deceit, misrepresentation, or subterfuge; or by the forgery or alteration of a prescription or of any written order; or by the concealment of a material fact; or by the use of a false name or the giving of a false address. The crime of fraudulently attempting to obtain a controlled substance shall include, but shall not be limited to nor be limited by, the following:

(1) Knowingly making a false statement in any prescription, order, report, or record, required by sections 195.005 to 195.425;

(2) For the purpose of obtaining a controlled substance, falsely assuming the title of, or representing oneself to be, a manufacturer, wholesaler, pharmacist, physician, dentist, podiatrist, veterinarian, or other authorized person;

(3) Making or uttering any false or forged prescription or false or forged written order;

(4) Affixing any false or forged label to a package or receptacle containing controlled substances;

(5) Possess a false or forged prescription with intent to obtain a controlled substance.

2. Fraudulently attempting to obtain a controlled substance is a class D felony.

3. Information communicated to a physician in an effort unlawfully to procure a controlled substance or unlawfully to procure the administration of any such drug shall not be deemed a privileged communication; provided, however, that no physician or surgeon shall be competent to testify concerning any information which he may have acquired from any patient while attending him in a professional character and which information was necessary to enable him to prescribe for such patient as a physician, or to perform any act for him as a surgeon.

4. The provisions of this section shall apply to all transactions relating to narcotic drugs under the provisions of section 195.080, in the same way as they apply to transactions under all other sections.

*(L. 1989 S.B. 215 & 58, A.L. 1997 H.B. 635)*

**195.246. Possession of ephedrine, penalty--possession is prima facie evidence of intent to violate section.**

1. It is unlawful for any person to possess any methamphetamine precursor drug with the intent to manufacture amphetamine, methamphetamine or any of their analogs.

2. Possession of more than twenty-four grams of any methamphetamine precursor drug or combination of methamphetamine precursor drugs shall be prima facie evidence of intent to violate this section. This subsection shall not apply to any practitioner or to any product possessed in the course of a legitimate business.

3. A person who violates this section is guilty of a class D felony.

*(L. 1996 H.B. 1301 & 1298, A.L. 2001 H.B. 471 merged with S.B. 89 & 37)*

**195.248. Marketing of ephedrine, penalty.**

1. It is unlawful for any person to market, sell, distribute, advertise or label any drug product containing ephedrine, its salts, optical isomers and salts of optical isomers, or pseudoephedrine, its salts, optical isomers and salts of optical isomers, for indication of stimulation, mental alertness, weight loss, appetite control, energy or other indications not approved pursuant to the pertinent federal over-the-counter drug Final Monograph or Tentative Final Monograph or approved new drug application.

2. A person who violates this section is guilty of a class D felony.

*(L. 1996 H.B. 1301 & 1298)*

**195.252. Distribution of controlled substance in violation of registration requirements, penalties.**

1. It is unlawful for any person:

(1) Who is subject to the provisions of sections 195.005 to 195.198 to distribute or dispense a controlled substance in violation of section 195.030;

(2) Who is a registrant, to manufacture a controlled substance not authorized by that person's registration, or to distribute or dispense a controlled substance not authorized by that person's registration to another registrant or other authorized person;

(3) To refuse or fail to make, keep or furnish any record, notification, order form, statement, invoice or information required under section 195.050.

2. Any person who violates subdivision (1) of subsection 1 of this section or subdivision (2) of subsection 1 of this section is guilty of a class D felony.

3. Any person who violates subdivision (3) of subsection 1 of this section is guilty of a class A misdemeanor.

*(L. 1989 S.B. 215 & 58)*

**195.400. Reports required, exceptions, penalties--person, defined--list of regulated chemicals.**

1. As used in sections 195.400 to 195.425 the term "person" means any individual, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.

2. Any manufacturer, wholesaler, retailer, or other person who sells, transfers, or otherwise furnishes any of the following substances to any person shall submit to the department of health and senior services a report, as prescribed by the department of health and senior services, of all such transactions:

(1) Anthranilic acid, its esters and its salts;

(2) Benzyl cyanide;

- (3) Ergotamine and its salts;
- (4) Ergonovine and its salts;
- (5) N-Acetylanthranilic acid, its esters and its salts;
- (6) Phenylacetic acid, its esters and its salts;
- (7) Piperidine and its salts;
- (8) 3,4,-Methylenedioxyphenyl-2-propanone;
- (9) Acetic anhydride;
- (10) Acetone;
- (11) Benzyl Chloride;
- (12) Ethyl ether;
- (13) Hydriodic acid;
- (14) Potassium permanganate;
- (15) 2-Butanone (or Methyl Ethyl Ketone or MEK);
- (16) Toluene;
- (17) Ephedrine, its salts, optical isomers, and salts of optical isomers;
- (18) Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers;
- (19) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers;
- (20) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers;
- (21) Methylamine and its salts;
- (22) Ethylamine and its salts;
- (23) Propionic anhydride;
- (24) Isosafrole;
- (25) Safrole;
- (26) Piperonal;
- (27) N-Methylephedrine, its salts, optical isomers and salts of optical isomers;
- (28) N-Methylpseudoephedrine, its salts, optical isomers and salts of optical isomers;
- (29) Benzaldehyde;
- (30) Nitroethane;

(31) Methyl Isobutyl Ketone (MIBK);

(32) Sulfuric acid;

(33) Iodine;

(34) Red phosphorous;

(35) Gamma butyrolactone;

(36) 1,4 Butanediol.

3. The department of health and senior services by rule or regulation may add substances to or delete substances from subsection 2 of this section in the manner prescribed pursuant to section 195.017, if such substance is a component of or may be used to produce a controlled substance.

*(L. 1989 S.B. 215 & 58, A.L. 1997 H.B. 635, A.L. 1998 H.B. 1147, ET AL., A.L. 2001 H.B. 471, A.L. 2010 H.B. 1965)*

**195.405.** (Repealed L. 2010 H.B. 1965 § A)

**195.410.** (Repealed L. 2010 H.B. 1965 § A)

**195.415.** (Repealed L. 2010 H.B. 1965 § A)

**195.417. Limit on sale or dispensing of certain drugs, exceptions--violations, penalty.**

1. The limits specified in this section shall not apply to any quantity of such product, mixture, or preparation which must be dispensed, sold, or distributed in a pharmacy pursuant to a valid prescription.

2. Within any thirty-day period, no person shall sell, dispense, or otherwise provide to the same individual, and no person shall purchase, receive, or otherwise acquire more than the following amount: any number of packages of any drug product containing any detectable amount of ephedrine, phenylpropanolamine, or pseudoephedrine, or any of their salts or optical isomers, or salts of optical isomers, either as:

(1) The sole active ingredient; or

(2) One of the active ingredients of a combination drug; or

(3) A combination of any of the products specified in subdivisions (1) and (2) of this subsection; in any total amount greater than nine grams, without regard to the number of transactions.

3. Within any twenty-four-hour period, no pharmacist, intern pharmacist, or registered pharmacy technician shall sell, dispense, or otherwise provide to the same individual, and no person shall purchase, receive, or otherwise acquire more than the following amount: any number of packages of any drug product containing any detectable amount of ephedrine, phenylpropanolamine, or pseudoephedrine, or any of their salts or optical isomers, or salts of optical isomers, either as:

(1) The sole active ingredient; or

(2) One of the active ingredients of a combination drug; or

(3) A combination of any of the products specified in subdivisions (1) and (2) of this subsection; in any total amount greater than three and six-tenths grams without regard to the number of transactions.

4. All packages of any compound, mixture, or preparation containing any detectable quantity of ephedrine, phenylpropanolamine, or pseudoephedrine, or any of their salts or optical isomers, or salts of optical isomers, except those that are excluded from Schedule V in subsection 17 or 18 of section 195.017, shall be offered for sale only from behind a pharmacy counter where the public is not permitted, and only by a registered pharmacist or registered pharmacy technician under section 195.017.

5. Each pharmacy shall submit information regarding sales of any compound, mixture, or preparation as specified in this section in accordance with transmission methods and frequency established by the department by regulation.

6. This section shall supersede and preempt any local ordinances or regulations, including any ordinances or regulations enacted by any political subdivision of the state. This section shall not apply to the sale of any animal feed products containing ephedrine or any naturally occurring or herbal ephedra or extract of ephedra.

7. All logs, records, documents, and electronic information maintained for the dispensing of these products shall be

open for inspection and copying by municipal, county, and state or federal law enforcement officers whose duty it is to enforce the controlled substances laws of this state or the United States.

8. Within thirty days of June 15, 2005, all persons who dispense or offer for sale pseudoephedrine and ephedrine products, except those that are excluded from Schedule V in subsection 17 or 18 of section 195.017, shall ensure that all such products are located only behind a pharmacy counter where the public is not permitted.

9. Any person who knowingly or recklessly violates this section is guilty of a class A misdemeanor.

*(L. 2001 H.B. 471 merged with S.B. 89 & 37, A.L. 2003 H.B. 470 merged with S.B. 39, A.L. 2005 H.B. 441 merged with S.B. 10 & 27, A.L. 2008 S.B. 724)*

*Effective 1-01-09*

**195.418. Limitations on the retail sale of methamphetamine precursor drugs--violations, penalty.**

1. The retail sale of methamphetamine precursor drugs shall be limited to:

(1) Sales in packages containing not more than a total of three grams of one or more methamphetamine precursor drugs, calculated in terms of ephedrine base, pseudoephedrine base and phenylpropanolamine base; and

(2) For nonliquid products, sales in blister packs, each blister containing not more than two dosage units, or where the use of blister packs is technically infeasible, sales in unit dose packets or pouches.

2. Any person holding a retail sales license pursuant to chapter 144, RSMo, who knowingly violates subsection 1 of this section is guilty of a class A misdemeanor.

3. Any person who is considered the general owner or operator of the outlet where ephedrine, pseudoephedrine, or phenylpropanolamine products are available for sale who violates subsection 1 of this section shall not be penalized pursuant to this section if such person documents that an employee training program was in place to provide the employee with information on the state and federal regulations regarding ephedrine, pseudoephedrine, or phenylpropanolamine.

*(L. 2001 H.B. 471 merged with S.B. 89 & 37)*

**195.425.** (Repealed L. 2010 H.B. 1965 § A)

**195.515. Copy of suspicious transaction report for certain drugs to be submitted to chief law enforcement officer, when--suspicious transaction defined--violations, penalty.**

1. Any manufacturer or wholesaler who sells, transfers, or otherwise furnishes ephedrine, pseudoephedrine or phenylpropanolamine, or any of their salts, optical isomers and salts of optical isomers, alone or in a mixture, and is required by federal law to report any suspicious transaction to the United States attorney general, shall submit a copy of the report to the chief law enforcement official with jurisdiction before completion of the sale or as soon as practicable thereafter.

2. As used in this section, "suspicious transaction" means any sale or transfer required to be reported pursuant to 21 U.S.C. 830(b)(1).

3. Any violation of this section shall be a class D felony.

*(L. 2001 S.B. 89 & 37)*

# BNDD REGULATIONS





# **DEPARTMENT OF HEALTH AND SENIOR SERVICES**

## **DIVISION 30: DIVISION OF REGULATION AND LICENSURE**

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**Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES**

**Division 30—Division of Health Standards and Licensure  
Chapter 1—Controlled Substances**

**19 CSR 30-1.002 Schedules of Controlled Substances**

*PURPOSE: Chapter 195, RSMo states in section 195.230, RSMo that the Department of Health shall prepare a list of all drugs falling within the purview of controlled substances. Upon preparation, a copy of the list shall be filed in the Office of the Secretary of State. It also requires, in section 195.017.11, RSMo, the Department of Health to revise and republish the schedules semiannually for two years from September 28, 1971, and annually after that.*

(1) Schedules of Controlled Substances.

(A) Schedule I shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name or brand name designated, listed in this section. Each drug or substance has been assigned the Drug Enforcement Administration (DEA) Controlled Substances Code Number set forth opposite it.

1. Opiates. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation:

A. Acetyl-alpha-methylfentanyl (N-(1-(1-methyl-2-phenethyl)-4-piperidinyl)-N-phenylacetamide)	9815
B. Acetylmethadol	9601
C. Allylprodine	9602
D. Alphacetylmethadol (except levo-alphacetylmethadol also known as levo-alpha-acetylmethadol levo-thadyl acetate or LAAM)	9603
E. Alphameprodine	9604
F. Alphamethadol	9605
G. Alpha-methylfentanyl (N-1-(alphamethyl-beta-phenyl) ethyl-4-piperidyl) propionanilide; 1-(1-methyl-2-phenylethyl)-4 ((N-propionilido) piperidine)	9814
H. Alpha-methylthiofentanyl (N-(1-methyl-2-(2-thienyl) ethyl-4-piperidinyl)-N-phenylpropanamide)	9832
I. Benzethidine	9606
J. Betacetylmethadol	9607
K. Beta-hydroxyfentanyl (N-(1-(2-hydroxy-2-phenethyl)-4-piperidinyl)-N-phenylpropanamide)	9830
L. Beta-hydroxy-3-methylfentanyl	

(other name: N-(1-(2-hydroxy-2-phenethyl)-3-methyl-4-piperidinyl)-N-phenylpropanamide)	9831
M. Betameprodine	9608
N. Betamethadol	9609
O. Betaprodine	9611
P. Clonitazene	9612
Q. Dextromoramide	9613
R. Diampromide	9615
S. Diethylthiambutene	9616
T. Difenoxin	9168
U. Dimenoxadol	9617
V. Dimepheptanol	9618
W. Dimethylthiambutene	9619
X. Dioxaphetyl butyrate	9621
Y. Dipipanone	9622
Z. Ethylmethylthiambutene	9623
AA. Etonitazene	9624
BB. Etoperidine	9625
CC. Furethidine	9626
DD. Hydroxypethidine	9627
EE. Ketobemidone	9628
FF. Levomoramide	9629
GG. Levophenacetyl morphan	9631
HH. 3-Methylfentanyl (N-(3-methyl-1-(2-phenylethyl)-4-piperidyl)-N-phenylpropanamide), its optical and geometric isomers, salts and salts of isomers	9813
II. 3-Methylthiofentanyl (N-((3-methyl-1-(2-thienyl) ethyl-4-piperidinyl)-N-phenylpropanamide)	9833
JJ. Morpheridine	9632
KK. MPPP (1-methyl-4-phenyl-4-propionoxypiperidine)	9661
LL. Noracetylmethadol	9633
MM. Norlevorphanol	9634
NN. Normethadone	9635
OO. Norpipanone	9636
PP. Para-fluorofentanyl (N-(4-fluorophenyl)-N-(1-(2-phenethyl)-4-piperidinyl) propanamide)	9812
QQ. PEPAP (1-(2-phenethyl)-4-phenyl-4-acetoxypiperidine)	9663
RR. Phenadoxone	9637
SS. Phenampromide	9638
TT. Phenomorphan	9647
UU. Phenoperidine	9641
VV. Piritramide	9642
WW. Proheptazine	9643
XX. Properidine	9644
YY. Propiram	9649
ZZ. Racemoramide	9645
AAA. Thiofentanyl	

(N-phenyl-N-(1-(2-thienyl)ethyl-4-piperidinyl)-propanamide	9835
BBB. Tilidine	9750
CCC. Trimeperidine	9646
2. Opium derivatives. Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, its salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:	
A. Acetorphine	9319
B. Acetyldihydrocodeine	9051
C. Benzylmorphine	9052
D. Codeine methylbromide	9070
E. Codeine-N-Oxide	9053
F. Cyrenorphine	9054
G. Desomorphine	9055
H. Dihydromorphine	9145
I. Drotebanol	9335
J. Etorphine (except hydrochloride salt)	9056
K. Heroin	9200
L. Hydromorphanol	9301
M. Methyldesorphine	9302
N. Methyldihydromorphine	9304
O. Morphine methylbromide	9305
P. Morphine methylsulfonate	9306
Q. Morphine-N-Oxide	9307
R. Myrophine	9308
S. Nicocodeine	9309
T. Nicomorphine	9312
U. Normorphine	9313
V. Pholcodeine	9314
W. Thebacon	9315
3. Hallucinogenic substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation, which contains any quantity of the following hallucinogenic substances or which contains any of its salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation (For purposes of paragraph (1)(A)3. of this rule only, the term isomer includes the optical, position and geometric isomers.):	
A. Alpha-ethyltryptamine	7249
Some trade or other names: etryptamine; Monase; alpha-ethyl-1H-indole-3-ethen-amine; 3-(2-aminobutyl)indole; alpha-ET and AET;	
B. Benzylpiperazine or other name BZP	7493
C. 4-bromo-2,5-dimethoxyamphetamine	7391
Some trade or other names: 4-bromo-2, 5-dimethoxy-a-methylphenethylamine; 4-bro-mo-2,5-DMA;	
D. 4-bromo-2,5-dimethoxyphenethylamine	7392
E. 2,5-dimethoxyamphetamine	7396
Some trade or other names: 2,5-dimethoxy-a-methylphenethylamine; 2,5-DMA;	
F. 2,5-dimethoxy-4-ethylamphetamine	7399

Some trade or other names: DOET	
G. 2,5-dimethoxy-4-(n)-propylthiophenethylamine	
H. 4-methoxyamphetamine	7411
Some trade or other names: 4-methoxy-a-methylphenethylamine; paramethoxyamphetamine; PMA;	
I. 5-methoxy-3,4-methylenedioxyamphetamine	7401
J. 4-methyl-2,5-dimethoxyamphetamine	7395
Some trade and other names: 4-methyl-2, 5-dimethoxy-a-methylphenethylamine; DOM; and STP;	
K. 3,4-methylenedioxy amphetamine	7400
L. 3,4-methylenedioxymethamphetamine (MDMA)	7405
M. 3,4-methylenedioxy-N-ethylamphetamine (also known as N-ethyl-alpha-methyl-3,4 (methylenedioxy) phenethylamine, N-ethyl MDA, MDE and MDEA)	7404
N. N-hydroxy-3,4-methylenedioxyamphetamine (also known as N-hydroxy-alpha-methyl-3,4-(methylenedioxy) phenethylamine and N-hydroxy MDA)	7402
O. 3,4,5-trimethoxy amphetamine	7390
P. Bufotenine	7433
Some trade and other names: 3-(b-Dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethyl-aminoethyl)-5-indolol; N, N-dimethylserotonin; 5-hydroxy-N,N-dimethyltryptamine; mappine;	
Q. Diethyltryptamine	7434
Some trade and other names: N, N-Diethyltryptamine; DET;	
R. Dimethyltryptamine	7435
Some trade or other names: DMT;	
S. Ibogaine	7260
Some trade and other names: 7-Ethyl-6,6b,7,8,9,10,12,13-octahydro-2-methoxy-6, 9-methano-5H-pyrido (1',2':1,2) azepino (5, 4-b) indole; Tabernanthe iboga;	
T. Lysergic acid diethylamide	7315
U. Marihuana	7360
Some trade or other names: marijuana;	
V. Mescaline	7381
W. Parahexyl	7374
Some trade or other names: 3-Hexyl-1-Hydroxy-7,8,9,10-tetrahydro-6,6,9-trimethyl-6H-dibenzo(b,d)pyran; Synhexyl;	
X. Peyote	7415
Meaning all parts of the plant presently classified botanically as Lophophora williamsii Lemaire, whether growing or not; the seeds thereof; any extract from any part of such plant; and every compound, manufacture, salt, derivative, mixture or preparation of such plant, its seeds or extracts;	
Y. N-ethyl-3-piperidyl benzilate	7482

Z. N-methyl-3-piperidyl benzilate	7484	5-phenyl-2-oxazoline; 4,5-dihydro-5-phenyl-2-oxazoline;	
AA. Psilocybin	7437	B. Cathinone (Some trade or other names: 2-amino-1-phenyl-1-propanone, alpha-amino-propio-phenone, 2-aminopropio-phenone and norephedrone)	1235
BB. Psilocyn	7438	C. Fenethylamine	1503
CC. Tetrahydrocannabinols	7370	D. Methcathinone	1585
Synthetic equivalents of the substances contained in the plant or in the resinous extractives of Cannabis, sp, synthetic substances, derivatives and their isomers, or both, with similar chemical structure and pharmacological activity such as the following:		Some trade or other names: 2-(methyl-amino)-propio-phenone; alpha-(methyl-amino)propio-phenone; 2-(methylamino)-1-phenylpropan-1-one; alpha-N-methylamino-propio-phenone; monomethylpropion; ephedrone; N-methylcathinone; methylcathinine; AL-464; AL-422; AL-463 and URI 432; its salts, optical isomers and salts of optical isomers;	
(I) D 1 cis or trans tetrahydrocannabinol and their optical isomers;		E. (±)cis-4-methylaminorex ((±)cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazoline)	1590
(II) D 6 cis or trans tetrahydrocannabinol and their optical isomers; and		F. N-ethylamphetamine	1475
(III) D 3, 4 cis or trans tetrahydrocannabinol and its optical isomers (Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions are covered.);		G. N,N-dimethylamphetamine	1480
DD. Ethylamine analog of phencyclidine	7455	(some other names: N,N-alpha-trimethyl-benzeneethanamine; N,N-alpha-trimethyl-phenethylamine), its salts, optical isomers and salts of optical isomers.	
Some trade or other names: N-ethyl-1-phenylcyclohexylamine, (1-phenylcyclohexyl) ethylamine, N-(1-phenylcyclohexyl)-ethylamine, cyclohexamine, PCE;		6. A temporary listing of substances subject to emergency scheduling under federal law shall include any material, compound, mixture or preparation which contains any quantity of the following substances:	
EE. Pyrrolidine analog of phencyclidine	7458	A. N-(1-benzyl-4-piperidyl)-N-phenylpropanamide (benzylfentanyl), its optical isomers, salts and salts of isomers	9818
Some trade or other names: 1(1-phenylcyclohexyl)-pyrrolidine PCPy, PHP;		B. N-(1-(2-thienyl) methyl-4-piperidyl)-N-phenylpropanamide (thenylfentanyl), its optical isomers, salts and salts of isomers	9834
FF. Thiophene analog of phencyclidine	7470	(B) Schedule II shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name or brand name designated, listed in this section. Each drug or substance has been assigned the Controlled Substances Code Number set forth opposite it.	
Some trade or other names: 1-(1-(2-thienyl)-cyclohexyl)-piperidine, 2-thienyl analog of phencyclidine, TCP, TCP;		1. Substances, vegetable origin or chemical synthesis. Unless specifically excepted or unless listed in another schedule, Schedule II shall include any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis opium and opiate; and any salt, compound, derivative or preparation of opium or opiate, excluding apomorphine, thebaine-derived butorphanol, dextrophan, nalbuphine, nalme-phen, naloxone and naltrexone and their respective salts, but including the following:	
GG. Trifluoromethylphenylpiperazine or other name		A. Raw opium	9600
TFMPP;		B. Opium extracts	9610
HH. 1-(1-(2-thienyl)cyclohexyl)pyrrolidine	7473		
Some other names: TCPy.			
4. Depressants. Unless specifically excepted or unless listed in another schedule, any material compound, mixture or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:			
A. Gamma-hydroxybutyric acid and other names GHB; gamma-hydroxybutyrate; 4-hydroxybutyrate; 4-hydroxybutonic acid; sodium oxybate; sodium oxybutyrate;			
B. Mecloqualone		2572	
C. Methaqualone		2565	
5. Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers and salts of isomers:			
A. Aminorex		1585	
Some trade or other names: aminoxaphen; 2-amino-			
130			

C. Opium fluid	9620	M. Levomethorphan	9210
D. Powdered opium	9639	N. Levorphanol	9220
E. Granulated opium	9640	O. Metazocine	9240
F. Tincture of opium	9630	P. Methadone	9250
G. Codeine	9050	Q. Methadone-Intermediate, 4-cyano-2-dimethylamino-4,4-diphenylbutane	9254
H. Ethylmorphine	9190	R. Moramide-Intermediate, 2-methyl-3-morpholino-1,1-diphenylpropane-carboxylic acid	9802
I. Etorphine hydrochloride	9059	S. Pethidine (Meperidine)	9230
J. Hydrocodone	9193	T. Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine	9232
K. Hydromorphone	9150	U. Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate	9233
L. Metopon	9260	V. Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid	9234
M. Morphine	9300	W. Phenazocine	9715
N. Oxycodone	9143	X. Piminodine	9730
O. Oxymorphone	9652	Y. Racemethorphan	9732
P. Thebaine	9333	Z. Racemorphan	9733
Any salt, compound, derivative or preparation thereof which is chemically equivalent or identical with any of the substances referred to in paragraph (1)(B)1. of this rule shall be included in Schedule II, except that these substances shall not include the isoquinoline alkaloids of opium; opium poppy and poppy straw; coca leaves	9040	AA. Remifentanil	9739
and any salt, compound, derivative or preparation of coca leaves including cocaine	9041	BB. Sufentanil	9740
and ecgonine	9180		
and their salts, isomers, derivatives and salts of isomers and derivatives and any salt, compound, derivative or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine	9041		
or ecgonine	9180		
and concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid or powder form which contains the phenanthrene alkaloids of the opium poppy)	9670		

2. Opiates. Unless specifically excepted or unless in another schedule any of the following opiates, including its isomers, esters, ethers, salts and salts of isomers, esters and ethers whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation, dextrophan and levopropoxyphene excepted:

A. Alfentanil	9737
B. Alphaprodine	9010
C. Anileridine	9020
D. Bezitramide	9800
E. Bulk Dextropropoxyphene (Non-dosage Forms)	9273
F. Butylnitrite no designated number	
G. Carfentanil	9743
H. Dihydrocodeine	9120
I. Diphenoxylate	9170
J. Fentanyl	9801
K. Isomethadone	9226
L. Levo-alphaacetylmethadol	9220
Some other names: levo-alphaacetylmethadol, levomethadyl acetate, LAAM	9648

3. Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

A. Amphetamine, its salts, optical isomers and salts of its optical isomers	1100
B. Methamphetamine, its salts, isomers and salts of its isomers	1105
C. Phenmetrazine and its salts	1631
D. Methylphenidate	1724

4. Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

A. Amobarbital	2125
B. Glutethimide	2550
C. Pentobarbital	2270
D. Phencyclidine	7471
E. Secobarbital	2315

5. Hallucinogenic substances:

A. Nabilone	7379
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Another name for nabilone: (±)trans-3-(1, 1-dimethylheptyl)-6, 6a,7,8,10,10a-hexahydro-1-hydroxy-6, 6-dimethyl-9H-dibenzo(b,d) pyran-9-one.

6. Immediate precursors. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances:

A. Immediate precursor to amphetamine and methamphetamine:

(I) Phenylacetone 8501

Some trade or other names: phenyl-2-propanone; P2P; benzyl methyl ketone; methyl benzyl ketone;

B. Immediate precursors to phencyclidine (PCP):

(I) 1-phenylcyclohexylamine 7460

(II) 1-piperidinocyclohexane-carbonitrile (PCC) 8603

(C) Schedule III shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name or brand name designated, listed in this section. Each drug or substance has been assigned the DEA Controlled Substances Code Number set forth opposite it.

1. Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position or geometric) and salts of such isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

A. Those compounds, mixtures or preparations in dosage unit form containing any stimulant substances listed in Schedule II which compounds, mixtures or preparations were listed on August 25, 1971, as excepted compounds under section 308.32 and any other drug of the quantitative composition shown in that list for those drugs or which is the same except that it contains a lesser quantity of controlled substances

	1405
B. Benzphetamine	1228
C. Chlorphentermine	1645
D. Clortermine	1647
E. Phendimetrazine	1615

2. Depressants. Unless specifically excepted or unless listed in another schedule, any material compound, mixture or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

A. Any compound, mixture or preparation containing:

(I) Amobarbital 2126

(II) Secobarbital 2316

(III) Pentobarbital 2271

or any salt thereof and one (1) or more other active medicinal ingredients which are not listed in any schedule;

B. Any suppository dosage form containing:

(I) Amobarbital 2126

(II) Secobarbital 2316

(III) Pentobarbital 2271

or any salt of any of these drugs and approved by the Food and Drug Administration for marketing only as a suppository;

C. Any substance which contains any quantity of a derivative of barbituric acid or any salt thereof

2100

D. Chlorhexadol 2510

E. Any drug product containing gamma hydroxybutyric acid, including its salts, isomers and salts of isomer, for which an application is approved under section 505 of the Federal Food, Drug and Cosmetic Act;

F. Ketamine 7285

G. Lysergic acid 7300

H. Lysergic acid amide 7310

I. Methyprylon 2575

J. Sulfondiethylmethane 2600

K. Sulfonethylmethane 2605

L. Sulfonmethane 2610

M. Tiletamine and zolazepam or any salt thereof 7295

Some trade or other names for a tiletamine-zolazepam combination product: Telazol.

Some trade or other names for tiletamine: 2-(ethylamino)-2-(2-thienyl)-cyclohexanone. Some trade or other names for zolazepam: 4-(2-fluorophenyl)-6-8-dihydro-1,3,8-trimethylpyrazolo-(3,4-e) (1,4)-diazepin-7(1H)-one, flupyrazapon.

3. Nalorphine 9400

4. Narcotics drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation containing limited quantities of any of the following narcotic drugs or any salts thereof:

A. Not more than 1.8 grams of codeine per one hundred milliliters (100 ml) or not more than ninety milligrams (90 mg) per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of

opium 9803

B. Not more than 1.8 grams of codeine per one hundred milliliters (100 ml) or not more than ninety milligrams (90 mg) per dosage unit, with one (1) or more active, non-narcotic ingredients in recognized therapeutic amounts 9804

C. Not more than three hundred milligrams (300 mg) of hydrocodone per one hundred milliliters (100 ml) or not more than fifteen milligrams (15 mg) per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium

9805

D. Not more than three hundred milligrams (300 mg) of hydrocodone per one hundred milliliters (100 ml) or not more than fifteen milligrams (15 mg) per dosage unit, with one (1) or more active nonnarcotic ingredients in recognized therapeutic amounts

9806

E. Not more than 1.8 grams of dihydrocodeine per one hundred milliliters (100 ml) or not more than ninety milligrams (90 mg) per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts

9807

F. Not more than three hundred milligrams (300 mg) of ethylmorphine per one hundred milliliters (100 ml) or not

more than fifteen milligrams (15 mg) per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts

9808

G. Not more than five hundred milligrams (500 mg) of opium per one hundred milliliters (100 ml) or per one hundred grams (100 g) or not more than twenty-five milligrams (25 mg) per dosage unit, with one (1) or more active nonnarcotic ingredients in recognized therapeutic amounts

9809

H. Not more than fifty milligrams (50 mg) of morphine per one hundred milliliters (100 ml) or per one hundred grams (100 g), with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts

9810

5. Anabolic steroids. Unless specially excepted or unless listed in another schedule, any material, compound, mixture or preparation containing any quantity of the following substances, including its salts, isomers and salts of isomers whenever the existence of such salts of isomers is possible within the specific chemical designation. DEA has assigned code 4000 for all anabolic steroids.

- A. Boldenone
- B. Chlorotestosterone (4-Chlortestosterone)
- C. Clostebol
- D. Dehydrochlormethyltestosterone
- E. Dihydrotestosterone (4-Dihydrotestosterone)
- F. Drostanolone
- G. Ethylestrenol
- H. Fluoxymesterone
- I. Formebolone (Formebolone)
- J. Mesterolone
- K. Methandienone
- L. Methandranone
- M. Methandriol
- N. Methandrostenolone
- O. Methenolone
- P. Methyltestosterone
- Q. Mibolerone
- R. Nandrolone
- S. Norethandrolone
- T. Oxandrolone
- U. Oxymesterone
- V. Oxymetholone
- W. Stanolone
- X. Stanozolol
- Y. Testolactone
- Z. Testosterone

AA. Trenbolone

BB. Any salt, ester, or isomer of a drug or substance described or listed in this subparagraph, if that salt, ester or isomer promotes muscle growth except an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the secretary of Health and Human Services for that administration.

6. Dronabinol (synthetic) in sesame oil and encapsulat-

ed in a soft gelatin capsule in a United States Food and Drug Administration approved drug product

7369

(Some other names for dronabinol: (6aR-trans)-6a,7,8,10a-tetrahydro-6.6.9-trimethyl-3-pentyl-6H-dibenzo (b,d) pyran-1-ol, or (-)

-delta-9-(trans)-tetrahydrocannabinol.)

(D) Schedule IV shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name or brand name designated, listed in this section. Each drug or substance has been assigned the DEA Controlled Substances Code Number set forth opposite it.

1. Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation containing limited quantities of any of the following narcotic drugs or any salts thereof:

A. Not more than one milligram (1 mg) of difenoxin (DEA Drug Code No. 9618) and not less than twenty-five micrograms (25 mcg) of atropine sulfate per dosage unit;

B. Dextropropoxyphene (alpha-(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-propionoxybutane)

9278

C. Narcotic drugs containing nonnarcotic active medicinal ingredients. Any compound, mixture or preparation containing any of the following limited quantities of narcotic drugs or salts thereof, which shall include one (1) or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

(I) Not more than two hundred milligrams (200 mg) of codeine per one hundred milliliters (100 ml) or per one hundred grams (100 g);

(II) Not more than one hundred milligrams (100 mg) of dihydrocodeine per one hundred milliliters (100 ml) or per one hundred grams (100 g); or

(III) Not more than one hundred milligrams (100 mg) of ethylmorphine per one hundred milliliters (100 ml) or per one hundred grams (100 g).

2. Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including its salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

A. Alprazolam	2882
B. Barbitol	2145
C. Bromazepam	2748
D. Camazepam	2749
E. Chloral betaine	2460
F. Chloral hydrate	2465
G. Chlordiazepoxide	2744
H. Clobazam	2751
I. Clonazepam	2737
J. Clorazepate	2768



K. Clotiazepam	2752	C. Fencamfamin	1780
L. Cloxazolam	2753	D. Fenproporex	1575
M. Delorazepam	2754	E. Mazindol	1605
N. Diazepam	2765	F. Mefenorex	1580
O. Dichloralphenazone	2467	G. Modafinil	1680
P. Estazolam	2756	H. Pemoline (including organometallic complexes and chelates thereof)	1530
Q. Ethchlorvynol	2540	I. Phentermine	1640
R. Ethinamate	2545	J. Pipradrol	1750
S. Ethyl loflazepate	2758	K. Sibutramine	1675
T. Fludiazepam	2759	L. SPA (-)-1-dimethylamino-1,2-diphenylethane	1635
U. Flunitrazepam	2763		
V. Flurazepam	2767	5. Other substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including its salts:	
W. Halazepam	2762	A. Pentazocine	9709
X. Haloxazolam	2771	B. Butorphanol (including its optical isomers)	9720
Y. Ketazolam	2772		
Z. Loprazolam	2773	6. Ephedrine. Any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system including their salts, isomers and salts of isomers:	
AA. Lorazepam	2885	A. Ephedrine or its salts, optical isomers or salts of optical isomers as the only active medicinal ingredient or contains ephedrine or its salts, optical isomers, or salts of optical isomers and therapeutically insignificant quantities of another active medicinal ingredient.	
BB. Lormetazepam	2774	(E) Schedule V shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name or brand name designated, listed in this subsection.	
CC. Mebutamate	2800	1. Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation containing any of the following narcotic drugs and their salts:	
DD. Medazepam	2836	A. Buprenorphine	9064
EE. Meprobamate	2820	2. Narcotic drugs containing nonnarcotic active medicinal ingredients. Any compound, mixture or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as follows, which shall include one (1) or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:	
FF. Methohexital	2264	A. Not more than two and five-tenths milligrams (2.5 mg) of diphenoxylate and not less than twenty-five micrograms (25 mcg) of atropine sulfate per dosage unit.	
GG. Methylphenobarbital (Mephobarbital)	2250	B. Not more than one hundred milligrams (100 mg) of opium per one hundred milliliters (100 ml) or per one hundred grams (100 g).	
HH. Midazolam	2884	C. Not more than five-tenths milligram (0.5 mg) of difenoxin (DEA Drug Code No. 9618) and not less than twenty-five micrograms (25 mcg) of atropine sulfate per	
II. Nimetazepam	2837		
JJ. Nitrazepam	2834		
KK. Nordiazepam	2838		
LL. Oxazepam	2835		
MM. Oxazolam	2839		
NN. Paraldehyde	2585		
OO. Petrichloral	2591		
PP. Phenobarbital	2285		
QQ. Pinazepam	2883		
RR. Prazepam	2764		
SS. Quazepam	2881		
TT. Temazepam	2925		
UU. Tetrazepam	2886		
VV. Triazolam	2887		
WW. Zaleplon	2781		
XX. Zolpidem	2783		
3. Fenfluramine. Any material, compound, mixture or preparation which contains any quantity of the following substances, including its salts, isomers (whether optical, position or geometric) and salts of such isomers, whenever the existence of such salts, isomers and salts of isomers is possible:			
A. Fenfluramine	1670		
4. Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers and salts of isomers:			
A. Cathine ((+)-norpseudoephedrine)	1230		
B. Diethylpropion	1610		

dosage unit.

3. Stimulants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system including its salts, isomers and salts of isomers:

A. Pyrovalerone 1485

(2) Excluded Nonnarcotic Substances. The following non-narcotic substances which, under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301), may be lawfully sold over the counter without a prescription, are excluded from all schedules pursuant to section 195.015(5), RSMo.

#### Excluded Nonnarcotic Products

Company	Trade Name	NDC Code	Form	Contr. Substance	mg or mg/ml
Bioline Laboratories	Theophed	00719-1945	TB	Phenobarbital	8.00
Goldline Laboratories	Guiaaphed Elixir	00182-1377	EL	Phenobarbital	4.00
Goldline Laboratories	Tedrigen Tablets	00182-0134	TB	Phenobarbital	8.00
Hawthorne Products, Inc.	Choate's Leg Freeze		LQ	Chloral hydrate	246.67
Parke-Davis & Co.	Tedral	00071-0230	TB	Phenobarbital	8.00
Parke-Davis & Co.	Tedral Elixir	00071-0242	EX	Phenobarbital	40.00
Parke-Davis & Co.	Tedral S.A.	00071-0231	TB	Phenobarbital	8.00
Parke-Davis & Co.	Tedral Suspension	00071-0237	SU	Phenobarbital	80.00
Parned Pharmacy	Asma-Ese	00349-2018	TB	Phenobarbital	8.10
Rondex Labs	Azma-Aids	00367-3153	TB	Phenobarbital	8.00
Smith Kline Consumer 250.00	Benzedrex	49692-0928	IN	Propylhexedrine	
Sterling Drug, Inc.	Bronkolixir	00057-1004	EL	Phenobarbital	0.80
Sterling Drug, Inc.	Bronkotabs	00057-1005	TB	Phenobarbital	8.00
Vicks Chemical Co.	Vicks Inhaler	23900-0010	IN	I-Desoxyephedrine	113.00
White Hall Labs	Primatene (P-tablets)	00573-2940	TB	Phenobarbital	8.00

**AUTHORITY:** sections 195.015 and 195.195, RSMo 2000.\* *Material found in this rule previously filed as 19 CSR 30-1.010. Original rule filed April 14, 2000, effective Nov. 30, 2000. Amended: Filed Jan. 31, 2003, effective July 30, 2003.*

\*Original authority: 115.015, RSMo 1971, amended 1989 and 195.195, RSMo 1957, amended 1971, 1989, 1993.

#### 19 CSR 30-1.004 List of Excepted Substances

**PURPOSE:** The Department of Health is authorized to except by rule any compound, mixture or preparation containing any stimulant or depressant substance if one or more active medicinal ingredients not having a stimulant or depressant effect on the central nervous system is included to negate the potential for abuse. The compounds, mixtures and preparations excluded are listed in this rule.

**PUBLISHER'S NOTE:** The publication of the full text of the material that the adopting agency has incorporated by reference in this rule would be unduly cumbersome or expensive. Therefore, the full text of that material will be made available to any interested person at both the Office of the Secretary of State and the Office of the adopting agency, pursuant to section 536.031.4, RSMo. Such material will be provided at the cost established by state law.

(1) Excepted Stimulant or Depressant Compounds-Exempt Prescription Products. The listed drugs in dosage unit form and any other drug of the quantitative composition shown

in Part 1300 to end of Title 21, the Code of Federal Regulations, April 1998 or which is the same except that it contains a lesser quantity of controlled substances or other substances which do not have a stimulant, depressant or hallucinogenic effect and which are restricted by law to dispensing or prescription, are excepted from the provisions of sections 195.030, 195.040, 195.050 and 195.100, RSMo as provided for in section 195.017.6(5) and .8(3), RSMo. The rules of the Drug Enforcement Administration, 21 CFR Part 1300 to the end of Title 21, are hereby incorporated by reference and made a part of this rule.

(2) Excepted Chemical Preparations-Exempt Chemical Preparations. The listed preparations in unit form and any other preparation of the quantitative composition shown in Part 1300 to end of Title 21, the Code of Federal Regulations, April 1998 which is the same except that it contains a lesser quantity of controlled substances or other substances which do not have a stimulant, depressant or hallucinogenic effect are excepted from the provisions of sections 195.030, 195.040, 195.050 and 195.110, RSMo as provided for in section 195.017.6(5) and .8(3), RSMo. The rules of the Drug Enforcement Administration, 21 CFR Part 1300 to the end of Title 21, are hereby incorporated by reference and made a part of this rule.

**AUTHORITY:** section 195.195, RSMo 1994.\* *Material found in this rule previously filed as 19 CSR 30-1.020. Original rule filed April 14, 2000, effective Nov. 30, 2000.*

\*Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.

#### 19 CSR 30-1.006 List of Exempt Anabolic Steroid Products

**PURPOSE:** This rule maintains a list of anabolic steroid products excluded from 19 CSR 30-1.002(1)(C)5. in conformance with federal law.

(1) Persons who in the course of legitimate business handle products listed in the Table of Exempt Anabolic Steroid Products in this section shall be exempt from the registration, records, reports, prescriptions, physical security and import and export requirements associated with Schedule III substances.

(A) Trade Name	Company	NDC or DIN No.
1. Androgyn L.A.	Forest Pharmaceuticals, St. Louis, MO	0456-1005
2. Andro-Estro 90-4	Rugby Laboratories, Rockville Center, NY	0536-1605
3. depANDROGYN	Forest Pharmaceuticals, St. Louis, MO	0456-1020
4. DEPO-T.E.	Quality Research Pharmaceuticals, Camel, IN	52765-257
5. depTESTROGEN	Martica Pharmaceuticals, Phoenix, AZ	51698-257
6. Duomone	Wintec Pharmaceutical, Pacific, MO	52047-360
7. DURATESTIN	W.E. Hauck, Alpharetta, GA	43797-016
8. DUO-SPAN II	Primedics Laboratories, Gardena, CA	0684-0102

9. Estratest	Solvay Pharmaceuticals, Marietta, GA	0032-1026	diol Valerate Injection		
10. Estratest HS	Solvay Pharmaceuticals, Marietta, GA	0032-1023	35. Testosterone Enanthate-Estra-	Steris Labs., Inc., Phoenix, AZ	0402-0360
11. Menogen	Sage Pharmaceuticals, Shreveport, LA	59243-570	diol Valerate Injection		
12. Menogen HS	Sage Pharmaceuticals, Shreveport, LA	59243-560	36. Tilapia Sex Reversal Feed (Investigational)	Rangen, Inc., Buhl, ID	
13. PAN ESTRA TEST	Pan American Labs, Covington, LA	0525-0175	37. Tilapia Sex Reversal Feed (Investigational)	Ziegler Brothers, Inc. Gardners, PA	
14. Premarin with	Ayerst Labs., Inc. Methyltestosterone New York, NY	0046-0879			
15. Premarin with	Ayerst Labs., Inc., Methyltestosterone New York, NY	0046-0878			
<b>Trade Name Company NDC or DIN No.</b>					
16. Synovex H Pellets in process	Syntex Animal Health, Palo Alto, CA				
17. Synovex H Pellets in process granulation	Syntex Animal Health, Palo Alto, CA				
18. Synovex Plus in-process granulation	Fort Dodge Animal Health, Fort Dodge, IA				
19. Synovex Plus in-process bulk pellets	Fort Dodge Animal Health, Fort Dodge, IA				
20. Testagen	Clint Pharmaceuticals, Nashville, TN	55553-257			
21. TEST-ESTRO Cypionates	Rugby Laboratories, Rockville Centre, NY	0536-9470			
22. Testoderm 4 mg/d	Alza Corp., Palo Alto, CA	17314-4608			
23. Testoderm 6 mg/d	Alza Corp., Palo Alto, CA	17314-4609			
24. Testoderm with Adhesive 6 mg/d	Alza Corp., Palo Alto, CA	17314-2836			
25. Testoderm in-process film	Alza Corp., Palo Alto, CA				
26. Testoderm with Adhesive in-process film	Alza Corp., Palo Alto, CA				
27. Testosterone Cyp 50 Estradiol Cyp 2	I.D.E.-Interstate, Amityville, NY	0814-7737			
28. Testosterone Cypionate- Estradiol Cypionate Injection	Best Generics, No. Miami Beach, FL	54274-530			
29. Testosterone Cypionate- Estradiol Cypionate Injection	Schein Pharmaceuticals, Port Washington, NY	0364-6611			
30. Testosterone Cypionate-Estra- diol Cypionate Injection	Steris Labs., Inc., Phoenix, AZ	0402-0257			
31. Testosterone Cypionate-Estra- diol Cypionate Injection	Goldline Labs, Ft. Lauderdale, FL	0182-3069			
32. Testosterone Cypionate-Estra- diol Cypionate Injection	The Upjohn Co., Kalamazoo, MI	0009-0253			
33. Testosterone Enanthate-Estra- diol Valerate Injection	Goldline Labs., Ft. Lauderdale, FL	0182-3073			
34. Testosterone Enanthate-Estra-	Schein Pharmaceuticals, Port Washington, NY	0364-6618			
<b>AUTHORITY: section 195.195, RSMo 1994.* Material found in this rule previously filed as 19 CSR 30-1.025. Original rule filed April 14, 2000, effective Nov. 30, 2000.</b>					
<b>*Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.</b>					
<b>19 CSR 30-1.008 List of Excluded Veterinary Anabolic Steroid Implant Products</b>					
<b>PURPOSE: This rule maintains a list of veterinary anabolic steroid products excluded from 19 CSR 30-1.002(1)(C)5. in conformance with federal law.</b>					
(1) The following products containing an anabolic steroid that are expressly intended for administration through implants to cattle or other nonhuman species and which have been approved by the Secretary of Health and Human Services for such administration and are excluded from all schedules pursuant to section 195.017.5, RSMo.					
<b>Trade Name Company NDC or DIN No.</b>					
(A) Component E-H	Vetlife, Inc., Norcross, GA				021641-002
(B) Component E-H	Elanco, Scarborough, ON				01968327
(C) Component TE-S	Vetlife, Inc., Norcross, GA				021641-004
(D) Component T-H	Vetlife, Inc., Norcross, GA				021641-006
(E) Component T-S	Vetlife, Inc., Norcross, GA				021641-005
(F) F-TO	Animal Health, Upjohn International, Kalamazoo, MI				00093351
(G) Finaplix-H	Hoechst Roussel Vet, Somerville, NJ				12799-807-10
(H) Finaplix-S	Hoechst Roussel Vet, Somerville, NJ				12799-807-07
(I) Heifer-oid	Anchor Division, Boehringer Ingelheim, St. Joseph, MO				
(J) Heifer-oid	Bio-Ceutic Division, Boehringer Ingelheim, St. Joseph, MO				
(K) Heifer-oid	Ivy Laboratories, Inc., Overland Park, KS				
(L) Implus-H	The Upjohn Co., Kalamazoo, MI				0009-0434-01
(M) Implus-H	Upjohn Co., Animal Health Division, Orangeville, ON				06-0434-01 01968327
(N) Revalor-G	Hoechst Roussel Vet, Somerville, NJ				12799-811

(O) Revalor-H	Hoechst Roussel Vet, Somerville, NJ	12799-810
(P) Revalor-S	Hoechst Roussel Vet, Somerville, NJ	12799-809
(Q) Synovex H	Fort Dodge Labs, Fort Dodge, IA	0856-3901
(R) Synovex H	Syntex Laboratories, Palo Alto, CA	
(S) Synovex Plus	Fort Dodge Labs, Fort Dodge, IA	0856-3904

**AUTHORITY:** section 195.195, RSMo 1994 and 195.017, RSMo Supp. 1999.\* Original rule filed April 14, 2000, effective Nov. 30, 2000.

\*Original authority: 195.017, RSMo 1971, amended 1987, 1989, 1994, 1996, 1997, 1998; 195.195, RSMo 1957, amended 1971, 1989, 1993.

## 19 CSR 30-1.010 Schedules of Controlled Substances

(Rescinded November 30, 2000)

**AUTHORITY:** section 195.195, RSMo Supp. 1993. This rule was previously filed as 13 CSR 50-130.010 and 19 CSR 10-130.010. Original rule filed Jan. 31, 1972, effective April 1, 1972. Amended: Filed Oct. 4, 1972, effective Oct. 14, 1972. Amended: Filed April 4, 1973, effective April 14, 1973. Amended: Filed Sept. 28, 1973, effective Nov. 4, 1973. Amended: Filed Jan. 3, 1974, effective Jan. 13, 1974. Amended: Filed Oct. 9, 1974, effective Oct. 19, 1974. Amended: Filed July 17, 1975, effective July 27, 1975. Amended: Filed Oct. 8, 1975, effective Oct. 18, 1975. Refiled: March 24, 1976. Amended: Filed Oct. 12, 1976, effective Jan. 13, 1977. Amended: Filed March 15, 1977, effective March 24, 1977. Amended: Filed Nov. 14, 1977, effective Nov. 6, 1977. Amended: Filed Sept. 28, 1977, effective Jan. 13, 1978. Amended: Filed March 9, 1978, effective Feb. 24, 1978. Amended: Filed Oct. 2, 1978, effective Sept. 27, 1978. Amended: Filed Nov. 14, 1978, effective June 16, 1978. Amended: Filed Nov. 14, 1978, effective Oct. 25, 1978. Amended: Filed Feb. 13, 1979, effective Feb. 9, 1979. Amended: Filed Feb. 19, 1980, effective Feb. 11, 1980. Amended: Filed Oct. 14, 1980, effective July 24, 1980. Amended: Filed Oct. 14, 1980, effective Aug. 21, 1980. Amended: Filed Oct. 14, 1981, effective Oct. 30, 1980. Amended: Filed Oct. 14, 1981, effective May 8, 1981. Amended: Filed Oct. 14, 1981, effective Aug. 20, 1981. Amended: Filed Nov. 1, 1982, effective Dec. 11, 1982. Amended: Filed Jan. 12, 1983, effective Feb. 11, 1983. Amended: Filed March 11, 1983, effective April 1, 1983. Amended: Filed Sept. 2, 1983, effective Dec. 11, 1983. Amended: Filed Nov. 7, 1983, effective Dec. 11, 1983. Amended: Filed July 12, 1984, effective Aug. 11, 1984. Amended: Filed Sept. 20, 1984, effective Nov. 11, 1984. Amended: Filed Jan. 15, 1985, effective Feb. 11, 1985. Amended: Filed May 29, 1985, effective June 27, 1985. Amended: Filed July 24, 1985, effective Aug. 26, 1985. Amended: Filed Sept. 12, 1985, effective Oct. 11, 1985. Changed to 19 CSR 10-130.010, effective Oct. 11, 1985. Amended: Filed Jan. 3, 1986, effective Jan. 16, 1986. Changed to 19 CSR 30-1.010, effective Aug. 11, 1986. Amended: Filed April 17, 1987, effective May 14, 1987. Amended: Filed July 3, 1987, effective Aug. 27,

1987. Amended: Filed May 3, 1988, effective May 26, 1988. Amended: Filed Sept. 25, 1989, effective Oct. 27, 1989. Emergency amendment filed April 3, 1991, effective April 13, 1991, expired Aug. 10, 1991. Emergency amendment filed May 1, 1991, effective May 11, 1991, expired Sept. 7, 1991. Emergency amendment filed July 23, 1991, effective Aug. 2, 1991, expired Nov. 28, 1991. Amended: Filed April 3, 1991, effective Sept. 30, 1991. Amended: Filed May 1, 1991, effective Sept. 30, 1991. Amended: Filed March 2, 1992, effective Aug. 6, 1992. Amended: Filed July 6, 1993, effective Dec. 9, 1993. Emergency amendment filed Jan. 5, 1994, effective Jan. 15, 1994, expired May 14, 1994. Amended: Filed Jan. 5, 1994, effective July 30, 1994. Rescinded: Filed April 14, 2000, effective Nov. 30, 2000.

*State v. Miller*, 588 SW2d 237 (Mo. App. 1979). Evidence of the presence of amphetamine is sufficient to support a controlled substances conviction; no quantitative analysis is necessary. Those rules refiled between January 1 and March 31, 1976 were not required to be published under section 536.021, RSMo. Also, courts must take judicial notice of the contents of the Code of State Regulations.

*Selvey v. State*, 578 SW2d 64 (Mo. App. 1979). Phenmetrazine, originally established statutorily as a Schedule III controlled substance, was rescheduled by the Division of Health to Schedule II. Such a rescheduling is within the statutory power granted the Division of Health and does not usurp the legislative power of the general assembly.

*State v. Davis*, 450 SW2d 168 (Mo. App. 1970). Statutes which direct the Division of Health to prepare a list of drugs classified as barbiturates and stimulants, the sale of which are made unlawful by statute, does not violate the Missouri Constitution prohibition in Article I, section 31 against delegation of authority to an agency to make a rule fixing a fine or imprisonment as punishment for its violation.

## 19 CSR 30-1.011 Definitions

**PURPOSE:** This rule contains definitions which establish the intended meaning of certain terms used throughout this chapter.

(1) As used in this chapter, the following terms shall have the meanings specified:

(A) Commercial container means any bottle, jar, tube, ampule or other receptacle in which a substance is held for distribution or dispensing to an ultimate user and, in addition, any box or package in which the receptacle is held for distribution or dispensing to an ultimate user. The term commercial container does not include any package liner, package insert or other material kept with or within a commercial container, nor any carton, crate, drug or other package in which commercial containers are stored or are used for shipment of controlled substances;

(B) Controlled substances administration record means the form used to record information when administering individual drug doses to patients;

(C) Dispenser means an individual practitioner, institutional practitioner, pharmacy or pharmacist who dispenses a controlled substance;

(D) Hospice means a public agency or private organization

or subdivision of either of these that is primarily engaged in providing care to dying persons and their families and meets the standards specified in 19 CSR 30-35;

(E) Hospital employee means a nurse, physician, pharmacist or other responsible patient-care employee;

(F) Individual practitioner means a physician, dentist, veterinarian, optometrist or other individual licensed, registered or otherwise permitted by the United States or Missouri to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy or an institutional practitioner;

(G) Institutional practitioner means a hospital or other person (other than an individual) licensed, registered or otherwise permitted by the United States or Missouri to dispense a controlled substance in the course of professional practice, but does not include a pharmacy;

(H) Long-term care facility means a nursing home, retirement care, mental care, or other facility or institution which provides extended health care to resident patients;

(I) Name means the official name, common or usual name, chemical name or brand name of a substance;

(J) Nurse means a registered or licensed practical nurse licensed under Chapter 335, RSMo;

(K) Patient care areas means any area of a hospital where medical attention is rendered to a patient;

(L) Pre-hospital emergency medical service means an emergency medical services system as defined in Chapter 190, RSMo providing services to persons prior to admission to a hospital;

(M) Prescription means an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user. (For example, an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription.);

(N) Readily retrievable means that certain records are kept by automatic data processing systems or other electronic or mechanized record keeping systems in a manner that they can be separated out from all other records; and/or records are kept on which certain items are asterisked, redlined, highlighted or in some other manner visually identifiable apart from other items appearing on the records; and records are provided within three working days of a request;

(O) Registration means a Missouri controlled substances registration;

(P) Reregistration means a registration issued to a person who was previously registered and whose application for reregistration was received by the Department of Health prior to the expiration of the previous registration;

(Q) Temporary location registration means a registration issued to an individual practitioner who:

1. Has a current Missouri professional license to practice and is registered with the Department of Health at the address listed on his/her professional license;

2. Has a federal Drug Enforcement Administration registration that is valid in Missouri;

3. Anticipates practicing in Missouri within the next 12 months;

4. Does not practice for more than 90 consecutive calendar days at any location;

5. Maintains a record of the date(s) and location(s) of all practice activity in Missouri and makes the record available to the Bureau of Narcotics and Dangerous Drugs. This record shall be retained for two years;

6. Maintains all required controlled substance records at each location;

7. Does not receive or stock controlled substances at any location;

(2) Any term not defined in this rule shall have the definition set forth in Chapter 195, RSMo.

*AUTHORITY: section 195.195, RSMo 2000.\* Original rule filed April 14, 2000, effective Nov. 30, 2000. Amended: Filed Jan. 31, 2003, effective July 30, 2003.*

*\*Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

### **19 CSR 30-1.013 Miscellaneous Fees**

*PURPOSE: This rule establishes and fixes certain fees and charges statutorily authorized to be made by the Department of Health in provisions codified in Chapters 195 and 610, RSMo.*

(1) Fees for copies of public records or other documents:

(A) Copy, per page \$ 0.25

(B) Research fee, per hour \$15.00

(2) Payment of fee may be required in advance.

(3) Fees are nonrefundable.

*AUTHORITY: section 195.030, RSMo Supp. 1999 and 195.195, RSMo 1994.\* Original rule filed April 14, 2000, effective Nov. 30, 2000.*

*\*Original authority: 195.030, RSMo 1939, amended 1971, 1989, 1993, 1995, 1997, 1999; 195.195, RSMo 1957, amended 1971, 1989, 1993.*

### **19 CSR 30-1.015 Registrations and Fees**

*PURPOSE: This rule establishes fees for various types of registration, a late registration fee, manner of payment, and exemption from the registration fee.*

(1) For each registration or re-registration to—

(A) Manufacture controlled substances, the registrant shall pay a fee of sixty-six dollars (\$66);

(B) Distribute controlled substances, the registrant shall pay a fee of sixty-six dollars (\$66);

(C) Dispense controlled substances listed in Schedules II–V including dispensing of controlled substances by individual practitioners in training programs or to conduct research or instructional activities with those substances, the registrant shall pay a fee of thirty dollars (\$30);

(D) Conduct research or instructional activities with a controlled substance listed in Schedule I, the registrant shall pay a fee of thirty dollars (\$30);

(E) Conduct chemical analysis with controlled substances listed in any schedule, the registrant shall pay a fee of thirty dollars (\$30); and

(F) Import or export controlled substances listed in any schedule, the registrant shall pay a fee of sixty-six dollars (\$66).

(2) Lapsed Registration Fee. A late charge of ten dollars (\$10) must be submitted with the original registration fee if an application is submitted more than fifteen (15) days after a previous registration has expired.

(3) Time and Method of Payment and Refunds. Registration and re-registration fees shall be paid at the time when the application for registration or re-registration is submitted for filing. This is a nonrefundable processing fee. Payment should be made in the form of a personal, certified, or cashier's check or money order made payable to Department of Health and Senior Services. Payments made in the form of stamps, foreign currency, or third-party endorsed checks will not be accepted. Applications and fees submitted electronically online shall use a credit card and use the online payment system provided on the department's website.

(4) Persons Exempt From Fee. The Department of Health and Senior Services shall exempt the following persons from payment of a fee for registration or re-registration:

(A) Any official or agency of the United States Army, Navy, Marine Corps, Air Force, Coast Guard, Veterans Administration, or Public Health Service who is authorized to procure or purchase controlled substances for official use;

(B) Any official, employee or other civil officer, or agency of the United States or state or any political subdivision or agency who is authorized to purchase controlled substances, to obtain these substances from official stocks, to dispense or administer these substances, to conduct research, instructional activities, or chemical analysis with these substances, or any combination of them, in the course of his/her official duties or employment;

(C) In order to claim exemption from payment of a registration or re-registration fee, the registrant shall apply for exemption by completing appropriate sections of the application;

(D) Exemption from payment of a registration or re-registration fee does not relieve the registrant of any other requirements or duties prescribed by law; and

(E) Any registration that is exempt from payment pursuant to this section shall be valid only when authorized persons are conducting activities in the course of their official duties or employment at their government practice location. If the person conducts controlled substance activities away from his or her government practice location, the person shall apply and submit the required fee

for a non-exempt registration.

*AUTHORITY: sections 195.030 and 195.195, RSMo 2000.\* Original rule filed April 14, 2000, effective Nov. 30, 2000. Amended: Filed Jan. 31, 2003, effective July 30, 2003. Amended: Filed April 29, 2011, effective Nov. 30, 2011.*

*\*Original authority: 195.030, RSMo 1939, amended 1971, 1989, 1993, 1995, 1997, 1999 and 195.195, RSMo 1957, amended 1971, 1989, 1993.*

## **19 CSR 30-1.017 Registration Process**

*PURPOSE: This rule establishes the period and expiration of registration, the process of applying for registration, and information required to complete an application for registration.*

(1) Database and Survey Process.

(A) Applicants may apply for and receive a registration that is effective for up to twelve (12) months.

(B) Applicants may apply with either a paper application or through the department's electronic online system.

(C) Simultaneously with completing an application for a controlled substances registration, practitioners may also complete an annual voluntary census to assist the department in determining practitioner shortages and underserved regions of the state. Required questions and fields for controlled substance registrations are marked with an asterisk (\*) in the electronic online system and on paper applications.

(2) Period of Registration.

(A) Any registration shall be current and effective for twelve (12) months from the date issued or until the expiration date assigned at the time the registration is issued. No person who is required to be registered shall conduct any activity for which registration is required without a current registration. No controlled substance activities shall take place after a registration expires until a new registration has been issued.

(B) At the time any registration is issued, the registration shall be assigned to one of twelve (12) groups which shall correspond to the months of the year. The expiration date of all registrations within any group shall be the last day of the month designated for that group.

(C) Registrations for manufacturers and distributors may be assigned to a single group, and the expiration date may be less than twelve (12) months from the date the registration was issued.

(D) Training program registrations may be assigned to a single group, and the expiration date may be less than twelve (12) months from the date the registration was issued.

(E) A certificate of registration shall be made available online and printable to the registrant which shall include the name and address of the registrant, the expiration date of the registration, and a registration number for the convenience of identifying a registration or a registrant.

The same registration number may be used for a new registration for the same person.

(3) Requirements for All Applicants.

(A) Any person who is required to be registered and who is not so registered may apply for registration at any time. No person required to be registered shall engage in any activity for which registration is required until the application for registration is processed and the registration is issued. All applications are for new registrations.

(B) Applications for registration shall be made on forms designated by the Department of Health and Senior Services. Application forms may be requested from the Missouri Department of Health and Senior Services, PO Box 570, Jefferson City, MO 65102-0570 or may be completed online and submitted electronically via the Missouri Department of Health and Senior Services' website at [www.health.mo.gov](http://www.health.mo.gov) along with the required fee.

(C) A written application in paper form shall contain the signature of the applicant and shall be provided to the Department of Health and Senior Services with any required fee. This is a nonrefundable processing fee.

(D) An application which does not contain or is not accompanied by the required information or fee may be denied sixty (60) days after notifying the applicant of the deficiency.

(E) An application may be withdrawn by making a written request to the Department of Health and Senior Services.

(F) A person who is registered may conduct activities with controlled substances in Schedules II, III, IV, and V, as authorized by statute, unless a registration is restricted as to schedules or activities because of a settlement agreement, probation, or other disciplinary action taken by the Department of Health and Senior Services, the Drug Enforcement Administration, or a professional licensing board. Authority to conduct activities with controlled substances in Schedule I requires a separate application and registration.

(4) All applicants shall make full, true, and complete answers on the application. The Department of Health and Senior Services may require an applicant to submit documents or written statements of fact relevant to the application as considered necessary to determine whether the application should be granted. The failure of the applicant to provide these documents or statements within sixty (60) days after being requested to do so shall be considered to be a waiver by the applicant of an opportunity to present these documents or facts for consideration in granting or denying the application.

(5) Applications for Individual Practitioner Registrations. Applications by physicians, veterinarians, optometrists, podiatrists, and researchers for Missouri Controlled Substance Registrations shall include:

(A) The applicant's full legal name (first name, middle name, and last name), including any suffixes such as junior, senior, or III, gender, race, and ethnicity;

(B) A listing of all addresses and practice locations where controlled substance activities will be taking place. The applicant's street addresses, cities, zip codes, counties, and state. The number of hours worked per week for each location shall be provided for performing direct patient care (non-hospital), administration, research, teaching, in-patient hospital care, and other. The applicant shall also identify his or her primary, principle practice location, where he or she spends the most time. This will be the principle practice address that appears on the controlled substances registration. A physical street address is required and post office box addresses shall not be accepted;

(C) Whether the application is for a physician, veterinarian, optometrist, podiatrist, or researcher;

(D) His or her anticipated drug activities such as administering, prescribing, or dispensing;

(E) The required fee and fee information. If claiming an exemption from a fee, the applicant shall identify the name of the government agency that employs him or her;

(F) His or her business telephone number, fax number, email address, federal controlled substances registration number, if applicable; professional degree, if applicable; and professional license number, if applicable. If the applicant has an application pending for a federal controlled substances registration number, the applicant shall indicate the application is pending;

(G) Whether the applicant, or any officer of a corporate applicant, or individual employed by any applicant having access to controlled substances, has ever entered a plea of guilty, no contest, nolo contendere, or otherwise been convicted of any violation of any state or federal law related to the possession, manufacture, distribution, dispensing, or prescribing of controlled substances. If the answer is yes, the applicant shall provide an explanation;

(H) If the applicant is an individual or a registrant that holds a professional license, whether he or she is currently licensed and registered to practice his or her profession under the laws of this state;

(I) If the applicant is not an individual or registrant that holds a professional license, the applicant shall answer yes or no to whether the applicant is currently authorized to conduct business under the laws of this state;

(J) Previous Discipline. If the applicant currently holds or has previously held a state or federal controlled substance registration or state professional license or registration, the applicant shall answer yes or no to whether the applicant's license, registration, or application or renewal thereof has ever been surrendered, revoked, suspended, denied, restricted, or placed on probation and if any such action is pending. If the answer is yes, the applicant shall provide an explanation;

(K) Whether the applicant is abusing or has abused or been treated for or diagnosed with addiction regarding controlled substances during the past year. For purposes of this subsection, "abusing" or "abused" means using or having used a controlled substance in a manner not authorized under Chapter 195, RSMo;

(L) Copies and attachments of any guilty pleas, convictions, or disciplinary actions identified in subsections (G) and (J) of this section, if the department does not already have them on file;

(M) The original signature of the individual applicant, if the application is submitted on paper;

(N) His or her Social Security number and date of birth (MM/DD/YYYY);

(O) The date the application is signed;

(P) What drug schedules the applicant is requesting authority in; and

(Q) A listing of mid-level practitioners by name and license number with whom applicant has agreements pursuant to Chapter 334, RSMo.

(6) Applications for Pharmacies and Businesses. Applications for retail pharmacies and ambulance services, ambulatory surgery centers, analytical laboratories, correctional centers, distributors, exporters, hospices, hospitals, importers, manufacturers, narcotic treatment programs, long-term care facility E-kits, teaching institutions, researchers, or other applicants not listed in sections (5)–(8), shall include:

(A) The applicant's full legal name, and if applicable, d/b/a name;

(B) The applicant's tax ID number, if applicable;

(C) The applicant's facility license number, if applicable, and federal controlled substances registration number. If the applicant has an application pending for a federal controlled substances registration number, the applicant shall indicate an application is pending;

(D) The applicant's email address;

(E) The applicant's principle Missouri business street address, city, state, county, and zip code as it will appear on the controlled substances registration certificate. Post office box numbers shall not be accepted. A separate mailing address may also be provided;

(F) The applicant's business telephone number and fax number;

(G) The applicant's type of business activity, licensure type, licensure agency, and license number;

(H) What controlled substance schedules the applicant is requesting authority in;

(I) The applicant's criminal history information as it pertains to controlled substance laws. The applicant shall answer yes or no as to whether the owner, CEO or administrator, corporate officer, medical director, pharmacist in charge, or any employee with access to controlled drugs has ever pled guilty, no contest, nolo contendere, or ever been convicted of any violation of state or federal law relating to controlled substances;

(J) Whether there are any previous or pending disciplinary actions regarding the applicant's professional license or any controlled substance registration, whether the applicant's privileges or authority have been revoked, surrendered, suspended, restricted, or placed on probation, or if any application for a state license or any drug registration has ever been denied;

(K) The application shall be submitted with the required fee and fee information. If claiming an exemption from a

fee, the applicant must identify the name of the government agency;

(L) Copies and attachments of any guilty pleas, convictions, or disciplinary actions identified in subsections (I) and (J) of this section, if the department does not already have them on file;

(M) If the applicant is a retail business, the applicant shall provide a letter from the Missouri Department of Revenue that documents that no Missouri taxes are due and the applicant is in good standing; and

(N) The applicant shall sign and date an application submitted on paper and may use the electronic process if applying online. An application may be signed by the owner, chief executive officer or administrator, corporate officer, medical director, or pharmacist in charge.

(7) Applications for Dentists. Applications for dentists with the degrees of D.D.S. or D.M.D. shall include:

(A) The applicant's full legal name (first name, middle name, and last name), including any suffixes such as junior, senior, or III;

(B) His or her Social Security number and date of birth (MM/DD/YYYY);

(C) The applicant's federal controlled substances registration number. If the applicant has an application pending for a federal controlled substances registration number, the applicant shall indicate the application is pending;

(D) The applicant's gender, race, and ethnicity;

(E) The applicant's email address;

(F) The applicant's primary specialty and any board certification;

(G) Whether the applicant is licensed to practice and conduct activities and the applicant's licensure type, license number, and name of licensing agency;

(H) What drug schedules the applicant is requesting to conduct activities in;

(I) The applicant's anticipated drug activities such as administering, prescribing, or dispensing;

(J) The applicant's street addresses, city, zip code, county, and state of their primary, principle practice location, where they spend the most time. This will be the address that appears on the controlled substances registration. Post office box numbers shall not be accepted. Applicants shall also provide any secondary practice locations and the number of chair-side work hours per week at each location. The number of hours worked per week for each location shall be provided for performing direct patient care (non-hospital), administration, research, teaching, in-patient hospital care, and other;

(K) The applicant's business phone number and fax number;

(L) The applicant's criminal history information as it pertains to controlled substance laws. The applicant shall answer yes or no as to whether the applicant or any employees with access to controlled drugs have ever pled guilty, no contest, nolo contendere, or ever been convicted of any violation of state or federal law relating to controlled substances;

(M) Information regarding any previous or pending dis-



ciplinary actions regarding the applicant's professional license or any controlled substance registration, as to whether the applicant's privileges or authority have been revoked, surrendered, suspended, restricted, or placed on probation, or if any application for a state license or any drug registration has ever been denied;

(N) Whether the applicant is abusing or has abused or been treated for or diagnosed with addiction regarding controlled substances during the past year. For purposes of this subsection, "abusing" or "abused" means using or having used a controlled substance in a manner not authorized under Chapter 195, RSMo;

(O) The application shall be submitted with the required fee and fee information. If claiming an exemption from a fee, the applicant shall identify the name of the government agency that employs him or her;

(P) The applicant shall provide copies and attachments of any guilty pleas, convictions, or disciplinary actions identified in subsections (L) and (M) of this section, if the department does not already have them on file; and

(Q) The applicant shall sign and date an application submitted on paper and may use the electronic process if applying online.

(8) Applications for Mid-Level Practitioners. Applications for mid-level practitioners as defined by 21 CFR 1300.01(b)(28) such as advanced practice nurses and physician assistants shall include:

(A) The applicant's full legal name (first name, middle name, and last name), including any suffixes such as junior, senior, or III;

(B) The applicant's social security number and date of birth (MM/DD/YYYY);

(C) The applicant's federal controlled substances registration number. If the applicant has an application pending for a federal controlled substances registration number, the applicant shall indicate the application is pending;

(D) The applicant's gender, race, and ethnicity;

(E) The applicant's email address;

(F) Whether the applicant is licensed to practice and conduct activities and the applicant's licensure type, license number, and name of licensing agency;

(G) What controlled substance schedules (III, IV, or V) the applicant is requesting to conduct activities in;

(H) Which physicians the applicant has collaborative or supervision agreements with;

(I) A copy of the applicant's collaborative or supervision agreements with physicians, and a list of controlled substances from each physician that the mid-level practitioner is authorized to conduct activities with, in that agreement;

(J) The applicant's street address, city, zip code, county, and state of the applicant's primary, principle practice location. This will be the principle address that appears on the controlled substances registration. Post office boxes shall not be accepted. Applicants shall also provide any secondary practice location addresses and the number of hours worked per week for each location for performing direct patient care (non-hospital), adminis-

tration, research, teaching, in-patient hospital care, and other;

(K) The applicant's business phone number and fax number;

(L) The applicant's criminal history information as it pertains to controlled substance laws. The applicant shall answer yes or no as to whether the applicant or any employee with access to controlled drugs has ever pled guilty, no contest, nolo contendere, or ever been convicted of any violation of state or federal law relating to controlled substances;

(M) Information regarding any previous or pending disciplinary actions regarding the applicant's professional license or any controlled substance registration, as to whether the applicant's privileges or authority have been revoked, surrendered, suspended, restricted, or placed on probation, or if any application for a state license or any drug registration has ever been denied;

(N) Whether the applicant has abused or been treated for or diagnosed with addiction regarding controlled substances during the past year. For purposes of this subsection, "abusing" or "abused" means using or having used a controlled substance in a manner not authorized under Chapter 195, RSMo;

(O) The application shall be submitted with the required fee and fee information. If claiming an exemption from a fee, the applicant shall identify the name of the government agency that employs the applicant;

(P) The applicant shall provide copies and attachments of any guilty pleas, convictions, or disciplinary actions identified in subsections (L) and (M) of this section, if the department does not already have them on file; and

(Q) The applicant shall sign and date an application submitted on paper and may use the electronic process if applying online.

*AUTHORITY: section 195.195, RSMo 2000.\* Original rule filed April 14, 2000, effective Nov. 30, 2000. Amended: Filed Jan. 31, 2003, effective July 30, 2003. Amended: Filed April 29, 2011, effective Nov. 30, 2011.*

*\*Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

## **19 CSR 30-1.019 Registration Location**

*PURPOSE: This rule establishes requirements for the physical location of a registration.*

(1) A controlled substance registration shall be issued at a U.S. Postal Service street address.

(2) A controlled substance registration shall be issued to an individual practitioner at a Missouri practice location where controlled substance and other patient care activities occur.

*AUTHORITY: section 195.195, RSMo 2000.\* Original rule filed April 14, 2000, effective Nov. 30, 2000. Amended: Filed Jan. 31, 2003, effective July 30, 2003. Amend-*

ed: Filed April 29, 2011, effective Nov. 30, 2011.

\*Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.

## **19 CSR 30-1.023 Registration Changes**

*PURPOSE: This rule establishes procedures for modifying an existing registration, describes the conditions under which a registration automatically terminates, and prohibits the transfer of a registration.*

### **(1) Modification of Registration.**

(A) Any registrant may apply to modify his/her registration to authorize the handling of controlled substances in additional schedules by submitting a request in writing to the department. No fee shall be required to be paid for the modification. The application for modification shall be handled in the same manner as an application for registration.

(B) Any registrant may request to modify his or her name or address as shown on the registration provided that such a modification does not constitute a change of ownership or location. The request shall be made in writing, and no fee shall be required to be paid for the modification. The request for changes may be submitted electronically using the department's online database system. Requests submitted in paper form shall contain the registrant's signature.

(C) When the registrant's name or address as shown on the registration changes, the registrant shall notify the Department of Health and Senior Services in writing, including the registrant's signature, prior to or within thirty (30) days subsequent to the effective date of the change. No fee shall be required to be paid for the modification.

### **(2) Termination of Registration.**

(A) The registration of any person shall terminate—

1. On the expiration date assigned to the registration at the time the registration was issued;
2. If and when the person dies;
3. If and when the person ceases legal existence;
4. If and when a business changes ownership, except—

A. The registration shall not terminate for thirty (30) days from the effective date of the change if the new owner applies for a registration within the thirty (30)-day period and the corresponding Drug Enforcement Administration registration remains effective as provided for by the Drug Enforcement Administration;

5. If and when the person discontinues business or changes business location, except—

A. The registration shall not terminate for thirty (30) days from the effective date of the change if the person applies for a new registration or modification within the thirty (30)-day period; or

6. Upon the written request of the registrant.

(B) A mid-level practitioner's registration shall be contingent upon the physician with whom he or she has entered into an agreement pursuant to Chapter 334,

RSMo, having a current and valid registration. When such physician's registration expires, closes, or is no longer valid, any mid-level practitioner(s) with whom he or she has entered into an agreement shall no longer have controlled substance authority. The mid-level practitioner(s) shall cease controlled drug activities until the physician has obtained a new registration or the mid-level practitioner(s) obtain(s) another agreement with another physician pursuant to Chapter 334, RSMo. Mid-level practitioners and any physician with whom he or she has entered into an agreement pursuant to Chapter 334, RSMo, shall notify the Department of Health and Senior Services of the termination of any such agreement.

(C) Any registrant who ceases legal existence or discontinues business or professional practice shall notify the Department of Health and Senior Services of the effective date of this action and promptly return his/her registration certificate to the Department of Health and Senior Services.

(3) Transfer of Registration. No registration or any authority conferred by registration shall be assigned or otherwise transferred.

*AUTHORITY: section 195.195, RSMo 2000.\* Original rule filed April 14, 2000, effective Nov. 30, 2000. Amended: Filed Jan. 31, 2003, effective July 30, 2003. Amended: Filed April 29, 2011, effective Nov. 30, 2011.*

\*Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.

## **19 CSR 30-1.025 List of Exempt Anabolic Steroid Products**

(Rescinded November 30, 2000)

*AUTHORITY: section 195.015.4, RSMo Supp. 1989. Original rule filed July 6, 1993, effective Dec. 9, 1993. Rescinded: Filed April 14, 2000, effective Nov. 30, 2000.*

## **19 CSR 30-1.026 Separate Registrations**

*PURPOSE: This rule defines the requirements for controlled substance registrations for separate activities and for separate sites, and defines when a separate registration is not required.*

(1) Independent Activities. The following eight groups of activities are deemed to be independent of each other and require separate registration:

(A) Manufacturing controlled substances;

(B) Distributing controlled substances, except:

1. A dispenser distributing less than 5% of the total combined dosage units of controlled substances distributed and dispensed in a calendar year shall be exempt from obtaining a separate registration for distributing;

2. A dispenser distributing more than 5% of the total combined dosage units of controlled substances distrib-

uted and dispensed in a calendar year must obtain a separate registration as a distributor but shall be exempt from maintaining separate inventories under 19 CSR 30-1.042;

(C) Dispensing controlled substances listed in Schedules II-V;

(D) Conducting research and instructional activities with controlled substances listed in Schedule I;

(E) Conducting research with controlled substances listed in Schedules II-V;

(F) Conducting a narcotic treatment program with narcotic controlled substances listed in Schedules II-V;

(G) Conducting instructional activities with controlled substances listed in Schedules II-V;

(H) Importing controlled substances;

(I) Exporting controlled substances;

(J) Conducting chemical analysis with controlled substances listed in any schedule.

(2) No activity shall be conducted with any controlled substance in any schedule not requested for and shown on the current registration.

(3) **Separate Locations.** A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed or dispensed by a person.

(A) For purposes of registration only, the following locations shall be deemed not to be places where controlled substances are manufactured, distributed or dispensed:

1. A warehouse where controlled substances are stored by or on behalf of a registered person, unless these substances are distributed directly from the warehouse to registrants other than the registered person or to persons not required to register;

2. An office used by agents of a registrant where sales of controlled substances are solicited, made or supervised but which neither contains these substances (other than substances for display purposes or lawful distribution as samples only) nor serves as a distribution point for filling sales orders;

3. An office used by a practitioner (who is registered at another location) where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner at the office and where no supplies of controlled substances are maintained;

4. A location on the immediate or contiguous property of a hospital, provided that the location is owned and operated by the hospital and controlled substances are not dispensed for use away from the location;

5. A separate location from a registered pre-hospital emergency medical service location where an emergency vehicle is housed that does not have a permanent location of operation and which rotates between locations at least every 30 days for operational reasons other than controlled substance registration;

6. A pre-hospital emergency medical service located outside the state of Missouri that renders assistance to

a pre-hospital emergency medical service located in the state of Missouri under a mutual aid contract in the case of an emergency, major catastrophe or other unforeseen event that jeopardizes the ability of the local Missouri pre-hospital emergency medical service to promptly respond.

(B) A separate registration is not required for each separate practice location for an individual practitioner who has a temporary location registration.

**AUTHORITY:** section 195.195, RSMo 1994.\* *Original rule filed April 14, 2000, effective Nov. 30, 2000.*

\**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

### **19 CSR 30-1.027 Investigative and Administrative Procedures**

**PURPOSE:** *This rule establishes procedures for the handling and disposition of information indicating violations of Chapter 195, RSMo by the Department of Health, pursuant to the mandates of section 195.040.*

(1) The Department of Health may allow officers of state and federal administrative agencies to attend and participate in informal conferences conducted with Missouri controlled substances registrants, Missouri regulated chemical registrants or applicants in order to assist the Department of Health in its deliberations.

**AUTHORITY:** section 195.195, RSMo 1994.\* *Original rule filed April 14, 2000, effective Nov. 30, 2000.*

\**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

### **19 CSR 30-1.030 Requirements for Controlled Substances Registration**

(Rescinded November 30, 2000)

**AUTHORITY:** section 195.195, RSMo 1994. *This rule was previously filed as 13 CSR 50-131.010. Original rule filed Jan. 31, 1972, effective April 1, 1972. Amended: Filed April 12, 1983, effective July 11, 1983. Amended: Filed May 31, 1989, effective Oct. 1, 1989. Amended: Filed Nov. 26, 1991, effective April 9, 1992. Amended: Filed Aug. 26, 1992, effective April 8, 1993. Amended: Filed Nov. 1, 1994, effective June 30, 1995. Rescinded: Filed April 14, 2000, effective Nov. 30, 2000.*

### **19 CSR 30-1.031 Physical Security Requirements**

**PURPOSE:** *This rule requires applicants and registrants to maintain security controls and procedures to prevent theft and diversion of controlled substances.*

(1) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls

against diversion, the Department of Health shall use the security requirement set forth in 19 CSR 30-1.032-19 CSR 30-1.034 as standards for the physical security controls and operating procedures necessary to prevent diversion. Substantial compliance with these standards may be deemed sufficient by the Department of Health after evaluation of the overall security system and needs of the applicant or registrant.

(2) Physical security controls shall be commensurate with the schedules and quantity of controlled substances in the possession of the registrant in normal business operations. If a controlled substance is transferred to a different schedule, or a noncontrolled substance is listed on any schedule, or the quantity of controlled substances in the possession of the registrant in normal business operations significantly increases, physical security controls shall be expanded and extended accordingly.

(3) All registrants who receive or transfer substantial quantities of controlled substances in normal business operations shall employ security procedures to guard against in-transit losses.

*AUTHORITY: section 195.195, RSMo 1994.\* Original rule filed April 14, 2000, effective Nov. 30, 2000.*

*\*Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

## **19 CSR 30-1.032 Security for Nonpractitioners**

*PURPOSE: This rule describes specific actions required of nonpractitioner registrants to maintain effective security.*

*PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.*

(1) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the federal Drug Enforcement Administration (DEA) or with the Department of Health and Senior Services to determine that the person is registered to possess the controlled substance.

(2) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Department of Health and Senior Services of suspicious orders

when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency.

(3) The registrant shall notify the Department of Health and Senior Services of any theft or significant loss of any controlled substances upon discovery of this theft or loss.

(A) The registrant shall complete and submit a Report of Loss, Theft or Diversion of Controlled Substances or Regulated Chemicals to the Department of Health and Senior Services no later than seven (7) business days after the discovery of such a loss. If the extent of the loss cannot be fully determined in that time frame, the registrant shall contact the Department of Health and Senior Services to request permission to submit an interim report and arrange for a complete report to be completed and submitted. The registrant may attach a copy of a completed Drug Enforcement Administration Loss Form in lieu of completing the back or second page of a Report of Loss, Theft or Diversion of Controlled Substances or Regulated Chemicals form. In the event of theft, diversion or suspected theft or diversion, the report submitted to the Department of Health and Senior Services shall be accompanied by or followed by a summary of the internal investigation performed, the outcome of the investigation, and a copy of any law enforcement agency report completed if applicable.

(B) If an insignificant amount of a controlled substance is lost during lawful activities authorized under Chapter 195, RSMo, the reason for the loss or a description of what occurred, the name of the drug and the amount lost shall be documented in writing, signed by the registrant and attached or filed with the last completed annual inventory.

(4) The registrant shall not distribute any controlled substance as a complimentary sample to any potential or current customer without the prior written request of the customer, to be used only for satisfying the legitimate medical needs of patients of the customer and only in reasonable quantities. The request must contain the name, address and registration number of the customer and the name of the specific controlled substance desired. The request shall be preserved by the registrant with other records of distribution of controlled substances. In addition, the requirements for order forms shall be complied with for any distribution of a controlled substance listed in Schedule I or II.

(5) Entities registered with the Department of Health and Senior Services as distributors shall be deemed to have met security requirements for storage of Schedule V controlled substance drug products containing ephedrine or pseudoephedrine if those products are stored in compliance and consistent with the regulated chemicals requirements set forth by the United States Drug Enforcement Administration and 21 CFR 1309.71 which is hereby incorporated by reference in this rule, as published on April 1, 2005 by the U.S. Government Printing

Office, U.S. Superintendent of Documents, Washington, DC 20402-001; [www.gpoaccess.gov/cfr/retrieve.html](http://www.gpoaccess.gov/cfr/retrieve.html). This rule does not incorporate any subsequent amendments or additions. Distributors will be required to conduct background checks on employees with access to these substances and to report losses of controlled substances as required in 19 CSR 30-1.034.

*AUTHORITY: sections 195.017, RSMo Supp. 2005 and 195.195, RSMo 2000.\* Original rule filed April 14, 2000, effective Nov. 30, 2000. Emergency amendment filed Aug. 18, 2005, effective Aug. 28, 2005, expired Feb. 23, 2006. Amended: Filed Sept. 1, 2005, effective Feb. 28, 2006.*

*\*Original authority: 195.017, RSMo 1971, amended 1987, 1989, 1994, 1996, 1997, 1998, 2001, 2005 and 195.195, RSMo 1957, amended 1971, 1989, 1993.*

### **19 CSR 30-1.033 Hearing Procedures on Controlled Substances Registration**

(Rescinded November 30, 2000)

*AUTHORITY: sections 195.040.11 and 195.195, RSMo Supp. 1989. Original rule filed Aug. 26, 1992, effective April 8, 1993. Rescinded: Filed April 14, 2000, effective Nov. 30, 2000.*

### **19 CSR 30-1.034 Security for Practitioners**

*PURPOSE: This rule describes specific actions required of practitioner registrants to maintain effective security. This rule also creates and defines the form which must be used by a registrant to report any theft or loss of controlled substances to the Department of Health.*

#### **(1) Physical Security.**

(A) Controlled substances listed in Schedules I and II shall be stored in a securely locked, substantially constructed cabinet.

(B) Controlled substances listed in Schedules III, IV and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies may disperse these substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

(C) This rule also shall apply to nonpractitioners authorized to conduct research or chemical analysis under another registration.

#### **(2) Other Security.**

(A) The registrant shall not employ as an agent or employee who has access to controlled substances any person who has been found guilty or entered a plea of guilty or nolo contendere in a criminal prosecution under the laws of any state or of the United States for any offense related to controlled substances or who has had an application for a state or federal controlled substance registration denied or has had his/her registration re-

voked or surrendered for cause at any time. For purposes of this subsection, the term for cause means a surrender in place of or as a consequence of any federal or state administrative, civil or criminal action resulting from an investigation of the individual's handling of controlled substances.

1. A registrant may apply in writing to the Department of Health and Senior Services for a waiver of subsection (2)(A) of this rule for a specific employee.

2. The Department of Health and Senior Services may issue a written waiver to any registrant upon determination that a waiver would be consistent with the public health and safety. In making this determination, the Department of Health and Senior Services shall consider—the duties of the employee, the circumstances surrounding the conviction, the length of time since the conviction was entered, whether a waiver has been granted by the federal Drug Enforcement Administration (DEA) pursuant to 21 CFR 1301.76, the security measures taken by the employer to prevent the theft and diversion of controlled substances, and any other factors consistent with public health and safety.

(B) A registrant shall notify the Department of Health and Senior Services of the theft, diversion or significant loss of any controlled substances or regulated chemicals upon discovery.

1. The registrant shall complete and submit a report of the loss or diversion of controlled substances to the Department of Health and Senior Services no later than seven (7) business days after the discovery of such a loss. The loss report form shall contain the following information: name and address of registrant, business phone number; Missouri Controlled Substance Registration Number; federal Drug Enforcement Administration Registration number; date of theft or loss; date of discovery of theft or loss; county of location; principal type of registration such as M.D., D.O., D.P.M., O.D., D.V.M., D.D.S., D.M.D., A.N.P., emergency medical service, pharmacy, hospital, manufacturer, nursing home, narcotic treatment program, teaching institution, distributor, importer, exporter, or other specified business; whether or not the loss or theft was reported to law enforcement; the name and phone number of the law enforcement agency reported to; the number of losses or thefts the registrant has experienced in the past twenty-four (24) months; the type of loss or diversion such as, break in/burglary, robbery, employee theft, forged or falsified records, lost in transit, or other explained type of loss; if lost in transit, the name of the common carrier and name of consignee; the name(s) of the individual diverting controlled substances who was responsible for the theft or loss; copy of registrant's internal investigative report involving the loss or theft; the full name, date of birth and Social Security number of the individual(s) responsible for the theft or diversion, if known; a copy of the police report if law enforcement was notified; if the loss or diversion was in transit, identify the origin of the delivery, the name of the carrier(s) used and the name of the consignee; a list of all controlled substances lost, stolen or diverted by their generic name, trade name, the dosage

strength, dosage form and quantity; the signature of the person completing the loss report and their title and the date of their signature. If the extent of the loss cannot be fully determined in that time

frame, the registrant shall contact the Department of Health and Senior Services to request permission to submit an interim report and arrange for a complete report to be completed and submitted. The registrant may attach a copy of a completed Drug Enforcement Administration Loss Form in lieu of completing the back or second page of a loss report form provided by the Department of Health and Senior Services. In the event of theft, diversion or suspected theft or diversion, the report submitted to the Department of Health and Senior Services shall be accompanied by or followed by a summary of the internal investigation performed, the outcome of the investigation, and a copy of any law enforcement agency report completed if applicable.

2. If an insignificant amount of a controlled substance is lost during lawful activities authorized under Chapter 195, RSMo, the reason for the loss or a description of what occurred, the name of the drug and the amount lost shall be documented in writing, signed by the registrant and attached or filed with the last completed annual inventory.

*AUTHORITY: section 195.195, RSMo 2000.\* Original rule filed April 14, 2000, effective Nov. 30, 2000. Amended: Filed Jan. 31, 2003, effective July 30, 2003.*

*\*Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

#### **19 CSR 30-1.035 Requirements for Prescribing, Dispensing and Administering Controlled Substances**

(Rescinded November 30, 2000)

*AUTHORITY: sections 195.040.3(2), 195.050.6 and 195.195, RSMo 1994. Original rule filed Nov. 14, 1988, effective Feb. 24, 1989. Amended: Filed Aug. 26, 1992, effective April 8, 1993. Amended: Filed Nov. 1, 1994, effective June 30, 1995. Rescinded: Filed April 14, 2000, effective Nov. 30, 2000.*

#### **19 CSR 30-1.036 Disposing of Unwanted Controlled Substances**

(Rescinded November 30, 2000)

*AUTHORITY: section 195.050.6, RSMo 1986. Original rule filed Jan. 18, 1989, effective April 27, 1989. Rescinded: Filed April 14, 2000, effective Nov. 30, 2000.*

#### **19 CSR 30-1.040 Dispensing and Distribution of Controlled Substances in Certain Situations**

(Rescinded July 30, 2003)

*AUTHORITY: section 195.195, RSMo 1986. This rule was previously filed as 13 CSR 50-132.010. Original rule filed Jan. 31, 1972, effective April 1, 1972. Rescind-*

*ed: Filed Jan. 31, 2003, effective July 30, 2003.*

#### **19 CSR 30-1.041 Records Requirements**

*PURPOSE: This rule defines the record keeping and inventory requirements for various classes of registrants.*

(1) Persons Required to Keep Records.

(A) Each registrant shall maintain the records and inventory required by 19 CSR 30-1.041-19 CSR 30-1.052, except as exempted by 19 CSR 30-1.041-19 CSR 30-1.052.

(B) Registered individual practitioners and institutional practitioners are required to keep records with respect to controlled substances which are prescribed, administered or dispensed.

(C) A registered person using any controlled substance in research conducted in conformity with an exemption granted under section 505(i) or 512(j) of the federal Food, Drug and Cosmetic Act (21 U.S.C. 355(i) or 360(j)) at a registered establishment which maintains records in accordance with either of those sections is not required to keep records if s/he notifies the Department of Health of the name, address and registration number of the establishment maintaining these records.

(D) A registered person using any controlled substance in preclinical research or in teaching at a registered establishment which maintains records with respect to these substances is not required to keep records if s/he notifies the Department of Health of the name, address and registration number of the establishment maintaining the records.

(E) Notice required by subsection (1)(D) of this rule shall be given at the time the person applies for registration or re-registration and shall be made in the form of an attachment to the application, which shall be filed with the application.

(2) Maintenance of Records and Inventories. Every inventory and other record required to be kept under 19 CSR 30-1.041-19 CSR 30-1.052, shall be kept by the registrant and be available, for at least two years from the date of the inventory or record, for inspecting and copying by authorized employees of the Department of Health, except that financial and shipping records (such as invoices and packing slips, but not executed order forms) may be kept at a central location rather than at the registered location if the registrant obtains from the Department of Health approval of his/her central record keeping system and a permit to keep central records. The permit to keep central records shall be subject to the following conditions:

(A) The permit shall specify the nature of the records to be kept centrally and the exact location where the records will be kept;

(B) The registrant agrees to deliver all or any part of these records to the registered location within three working days of receipt of a written request from the Department of Health for these records and if the Department of Health chooses to do so in lieu of requiring delivery of records to the registered location, to allow

authorized employees of the Department of Health to inspect the records at the central location upon request by the employees without a warrant of any kind;

(C) The failure of the registrant to perform his/her agreements under the permit shall revoke, without further action, the permit and all other such permits held by the registrant under other registrations. In the event of a revocation of other permits under subsection (2)(C) of this rule, the registrant, within 30 days after the revocation, shall comply with the requirement that all records be kept at the registered location.

(3) Each registered individual practitioner, institutional practitioner, manufacturer, distributor, importer and exporter shall maintain inventories and records of controlled substances as follows:

(A) Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant;

(B) Inventories and records of controlled substances listed in Schedules III, IV and V shall be maintained either separately from all other records of the registrant or in a form that the information required is readily retrievable from the ordinary business records of the registrant.

(4) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

(A) Inventories and records of all controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy and prescriptions for these substances shall be maintained in a separate prescription file;

(B) Inventories and records of controlled substances listed in Schedules III, IV and V shall be maintained either separately from all other records of the pharmacy or in a form that the information required is readily retrievable from ordinary business records of the pharmacy and prescriptions for those substances shall be maintained in a separate prescription file.

*AUTHORITY: sections 195.050 and 195.195, RSMo 1994 and 195.030, RSMo Supp. 1999.\* Original rule filed April 14, 2000, effective Nov. 30, 2000.*

*\*Original authority: 195.030, RSMo 1939, amended 1971, 1989, 1993, 1997, 1999; 195.050, RSMo 1939, amended 1971, 1989; 195.195, RSMo 1957, amended 1971, 1989, 1993.*

## **19 CSR 30-1.042 Inventory Requirements**

*PURPOSE: This rule defines requirements for the form and maintenance of controlled substance inventories.*

(1) General Requirements.

(A) Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory was taken. Controlled substances shall be deemed to be on hand if they are in the possession of or under the control of the registrant, including

substances returned by a customer, substances ordered by a customer but not yet invoiced, substances stored in a warehouse on behalf of the registrant and substances in the possession of employees of the registrant and intended for distribution as complimentary samples.

(B) A separate inventory shall be made by a registrant for each registered location. In the event controlled substances are in the possession or under the control of the registrant at a location for which s/he is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. Each inventory for a registered location shall be kept at the registered location.

(C) A separate inventory shall be made by a registrant for each independent activity for which s/he is registered.

(D) A registrant may take an inventory either as of the opening of business or as of the close of business on the inventory date. The registrant shall indicate on the inventory records whether the inventory is taken as of the opening or as of the close of business and the date the inventory is taken.

(E) An inventory must be maintained in a permanent written, typewritten or printed form. An inventory taken by use of an oral recording device must be transcribed promptly.

(2) Initial Inventory Date.

(A) Every person required to keep records who is registered with the Department of Health after May 1, 1971 and who was not registered previously shall take an inventory of all stocks of controlled substances on hand on the date s/he first engages in the manufacture, distribution or dispensing of controlled substances.

(B) Compliance with federal initial inventory date requirements is deemed satisfactory. Duplicate inventories are not required.

(3) Annual Inventory Date. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least once a year. The annual inventory may be taken on any date that is within one year of the previous annual inventory date.

(4) Inventory Date for Newly Controlled Substances. On the effective date of a rule by the Department of Health adding a substance to any schedule of controlled substances, which substance was not listed immediately prior to that date in any such schedule, every registrant required to keep records who is manufacturing, distributing or dispensing that substance shall take inventory of all stocks of the substance on hand. After that, this substance shall be included in each inventory made by the registrant.

(5) Inventories of Manufacturers. Each registered manufacturer shall include the following information in his/her inventory:

(A) For each controlled substance in bulk form to be used in (or capable of use in) the manufacture of the

same or other controlled or noncontrolled substances in finished form, the name of the substance and the total quantity of the substance to the nearest metric unit weight consistent with unit size (except that for inventories made in 1971, avoirdupois weights may be utilized where metric weights are not readily available);

(B) For each controlled substance in the process of manufacture on the inventory date the name of the substance, the quantity of the substance in each batch, stage of manufacture, or both, identified by the batch number or other appropriate identifying number and the physical form which the substance is to take upon completion of the manufacturing process (for example, granulations, tablets, capsules or solutions), identified by the batch number or other appropriate identifying number and if possible the finished form of the substance (for example, ten milligram (10 mg) tablet or ten milligram (10 mg) concentration per fluid ounce or milliliter) and the number or volume;

(C) For each controlled substance in finished form, the name of the substance; each finished form of the substance (for example, ten milligram (10 mg) tablet or ten milligram (10 mg) concentration per fluid ounce or milliliter); the number of units or volume of each finished form in each commercial container (for example, four 100 tablet bottles or three milliliter (3 ml) vials); the number of commercial containers of each finished form (for example, four 100 tablet bottles or six three milliliter (3 ml) vials);

(D) For each controlled substance not included in subsections (5)(A)-(C) of this rule (for example, damaged, defective or impure substances awaiting disposal, substances held for quality control purposes or substances maintained for extemporaneous compoundings), the name of the substance; the total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; the reason for the substance being maintained by the registrant and whether the substance is capable of use in the manufacture of any controlled substance in finished form.

(6) Inventories of Distributors. Each registered distributor shall include in his/her inventory the same information required of manufacturers in subsections (5)(C) and (D) of this rule.

(7) Inventories of Dispensers and Researchers. Each person registered to dispense or conduct research with controlled substances and required to keep records shall include in his/her inventory the same information required of manufacturers in subsections (5)(C) and (D) of this rule. In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the dispenser shall do as follows:

(A) If the substance is listed in Schedule I or II, s/he shall make an exact count or measure of the contents;

(B) If the substance is listed in Schedule III, IV or V, s/he shall make an estimated count or measure of the contents, unless the container holds more than 1,000

tablets or capsules in which case s/he must make an exact count of the contents.

(8) Inventories of Importers and Exporters. Each registered importer or exporter shall include in his/her inventory the same information required of manufacturers in subsections (5)(A), (C) and (D) of this rule. Each registered importer and exporter who also is registered as a manufacturer or as a distributor shall include in his/her inventory as an importer or exporter only those stocks of controlled substances that actually are separated from his/her stocks as a manufacturer or as a distributor (for example, in-transit or in storage for shipment).

(9) Inventories for Chemical Analysts. Each analytical laboratory registered to conduct chemical analysis with controlled substances shall include in its inventory the same information required of manufacturers in subsections (5)(A), (C) and (D) of this rule as to substances which have been manufactured, imported or received by the laboratory conducting the inventory. If less than one kilogram (1 kg) of any controlled substance (other than a hallucinogenic controlled substance listed in Schedule I) or less than twenty grams (20 g) of a hallucinogenic substance listed in Schedule I (other than lysergic acid diethylamide) or less than point five gram (0.5 g) of lysergic acid diethylamide, is on hand at the time of inventory, those substances need not be included in the inventory. Laboratories of the division may process up to one hundred fifty grams (150 g) of any hallucinogenic substance in Schedule I without regard to a need for an inventory of those substances.

*AUTHORITY: sections 195.030, RSMo Supp. 1999 and 195.195, RSMo 1994. \* Original rule filed April 14, 2000, effective Nov. 30, 2000.*

*\*Original authority: 195.030, RSMo 1939, amended 1971, 1989, 1993, 1995, 1997, 1999; 195.195, RSMo 1957, amended 1971, 1989, 1993.*

## **19 CSR 30-1.044 Continuing Records General Requirements**

*PURPOSE: This rule sets requirements for the maintenance of ongoing controlled substance records.*

(1) Every registrant required to keep records shall maintain on a current basis a complete and accurate record of each such substance manufactured, imported, received, sold, delivered, exported or otherwise disposed of by him/her.

(2) Separate records shall be maintained by a registrant for each registered location except as provided in 19 CSR 30-1.041(2). In the event controlled substances are in the possession or under the control of a registrant at a location for which s/he is not registered, the substance shall be included in the records of the registered location to which they are subject to control or to which the person possessing the substance is responsible.



(3) Separate records shall be maintained by a registrant for each independent activity for which s/he is registered.

(4) In recording dates of receipt, importation, distribution, exportation or other transfers, the date on which the controlled substances are actually received, imported, distributed, exported or otherwise transferred shall be used as the date of receipt or distribution of any documents of transfer (for example, invoices or packing slips).

(5) Records must be provided to the Department of Health within three working days upon request.

*AUTHORITY: sections 195.050 and 195.195, RSMo 1994.\* Original rule filed April 14, 2000, effective Nov. 30, 2000.*

*\*Original authority: 195.050, RSMo 1939, amended 1971, 1989; 195.195, RSMo 1957, amended 1971, 1989, 1993.*

### **19 CSR 30-1.046 Records for Manufacturers, Distributors, Importers and Exporters**

*PURPOSE: This rule sets requirements for record keeping by manufacturers, distributors, importers and exporters of controlled substances.*

(1) Records for Manufacturers. Each registered manufacturer shall maintain records with the following information:

(A) For each controlled substance in bulk form to be used in or capable of use in or being used in the manufacture of the same or other controlled or noncontrolled substances in finished form-

1. The name of the substance;
2. The quantity manufactured in bulk form by the registrant, including the date, quantity and batch or other identifying number of each batch manufactured;
3. The quantity received from other persons including the date and quantity of each receipt and the name, address and registration number of the other person from whom the substance was received;
4. The quantity imported directly by the registrant (under a registration as an importer) for use in manufacture by him/her, including the date, quantity and import permit or declaration number for each importation;
5. The quantity used to manufacture the same substance in finished form including the date and batch or other identifying number of each manufacture; the quantity used in the manufacture; the finished form (for example, ten milligram (10 mg) tablets or ten milligram (10 mg) concentration per fluid ounce or milliliter); the number of units of finished form manufactured; the quantity used in quality control; the quantity lost during manufacturing and the causes for the loss, if known; the total quantity of the substance contained in the finished form; the theoretical and actual yields and other information as is necessary to account for all controlled substances

used in the manufacturing process;

6. The quantity used to manufacture other controlled and noncontrolled substances, including the name of each substance manufactured and the information required in paragraph (1)(A)5. of this rule;

7. The quantity distributed in bulk form to other persons, including the date and quantity of each distribution and the name, address and registration number of each person to whom a distribution was made;

8. The quantity exported directly by the registrant, including the date, quantity and export permit or declaration number of each exportation;

9. The quantity distributed or disposed of in any other manner by the registrant (for example, distribution of complimentary samples or by destruction) including the date and manner of distribution or disposal, the name, address and registration number of the person to whom distributed and the quantity distributed or disposed;

(B) For each controlled substance in finished form-

1. The name of the substance;
2. Each finished form (for example, ten milligram (10 mg) tablet or ten milligram (10 mg) concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (for example, 100 tablet bottle or three milliliter (3 ml) vial);
3. The number of containers of each such commercial finished form manufactured from bulk form by the registrant, including the information required in paragraph (1)(A)5. of this rule;
4. The number of units of finished forms, commercial containers, or both, received from other persons, including the date of and number of units, commercial containers, or both, in each receipt and the name, address and registration number of the person from whom the units were received;
5. The number of units of finished form, commercial containers, or both, imported directly by the registrant, including the date of and the number of units, commercial containers, or both, in each importation;
6. The number of units, commercial containers, or both, manufactured by the registrant from units in finished form received from others or imported including: the date and batch or other identifying number of each manufacture; the operation performed (for example, repackaging or relabeling); the number of units of finished form used in the manufacture, the number manufactured and the number lost during the manufacture, with the causes for these losses, if known, and other information as is necessary to account for all controlled substances used in the manufacturing process;
7. The number of commercial containers distributed to other persons including the date of and number of containers in each distribution and the name, address and registration number of the person to whom the containers were distributed;
8. The number of commercial containers exported directly by the registrant, including the date, number of containers and export permit or declaration number for each exportation;
9. The number of units of finished forms, commercial

containers, or both, distributed or disposed of in any other manner by the registrant (for example, by distribution of complimentary samples or by destruction), including the date and manner of distribution

or disposal, the name, address and registration number of the person to whom distributed and the quantity in finished form distributed or disposed.

(2) Records for Distributors. Each registered distributor shall maintain records with the following information for each controlled substance:

(A) The name of the substance;

(B) Each finished form (for example, ten milligram (10 mg) tablet or ten milligram (10 mg) concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (for example, 100 tablet bottle or three milliliter (3 ml) vial);

(C) The number of commercial containers of each such finished form received from other persons, including the date of and number of containers in each receipt and the name, address and registration number of the person from whom the containers were received;

(D) The number of commercial containers of each finished form imported directly by the registrant including the date of and the number of containers in each importation;

(E) The number of commercial containers of each finished form distributed to other persons, including the date of and number of containers in each distribution and the name, address and registration number of the person to whom the containers were distributed;

(F) The number of commercial containers of the finished form exported directly by the registrant, including the date of and the number of containers in each exportation;

(G) The number of units or volume of finished forms, commercial containers, or both, distributed or disposed of in any other manner by the registrant (for example, by distribution as complimentary samples) including the date and manner of distribution or disposal, the name, address and registration number of the person to whom distributed and the quantity of the substance in finished form distributed or disposed.

(3) Records for Importers. Each registered importer shall maintain records with the following information for each controlled substance:

(A) The name of the substance;

(B) The quantity (or number of units or volume in finished form) imported, including the date, quantity (or number of units or volume) and import permit or declaration number for each importation;

(C) The quantity (or number of units or volume in finished form) distributed to other persons, including the date, quantity (or number of units or volume) of each distribution and the name, address and registration number of each person to whom a distribution was made;

(D) The quantity disposed of in any other manner by the registrant except quantities used in manufacturing by an importer under a registration as a manufacture,

which quantities are to be recorded, including the date and manner of disposal and the quantity disposed.

(4) Records for Exporters. Each registered exporter shall maintain records with the following information for each controlled substance:

(A) The name of the substance;

(B) The quantity (or number of units or volume in finished form) received from other persons, including the date and quantity (or number of units or volume) of each receipt and the name, address and registration number of each person from whom the substance was received;

(C) The quantity (or number of units or volume in finished form) exported, including the date, quantity (or number of units or volume) and the export permit or declaration number for each exportation, but excluding all quantities (and numbers of units and volumes) manufactured by an exporter under a registration as a manufacture, which quantities (and numbers of units and volumes) are to be recorded;

(D) The quantity disposed of in any other manner by the registrant including the date and manner of disposal and the quantity disposed.

*AUTHORITY: sections 195.050 and 195.195, RSMo 1994.\* Original rule filed April 14, 2000, effective Nov. 30, 2000.*

*\*Original authority: 195.050, RSMo 1939, amended 1971, 1989; 195.195, RSMo 1957, amended 1971, 1989, 1993.*

## **19 CSR 30-1.048 Records for Practitioners and Researchers**

*PURPOSE: This rule sets requirements for record keeping for individual practitioners and researchers. It also sets requirements for the use of facsimile and electronic computer transmission of controlled substance prescriptions.*

(1) Each individual practitioner, institutional practitioner and pharmacy shall maintain records with the following information for each controlled substance received, maintained, dispensed or disposed:

(A) The name of the substance;

(B) Each finished form (for example, ten milligram (10 mg) tablet or ten milligram (10 mg) concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (for example, 100 tablet bottle or three milliliter (3 ml) vial);

(C) The number of commercial containers of each finished form received from other persons, including the date of and number of containers in each receipt and the name, address and registration number of the person from whom the containers were received;

(D) The number of units or volume of the finished form dispensed including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed and the written or typewritten name or initials of the individual who dispensed or administered the substance;

(E) The number of units or volume of the finished forms, commercial containers, or both, disposed of in any other manner by the registrant, including the date and manner of disposal and the quantity of the substance in finished form disposed.

(2) Each individual practitioner shall maintain a record of the date, full name and address of the patient, the drug name, strength, dosage form and quantity for all controlled substances prescribed or administered. This record may be maintained in the patient's medical record. When the controlled substance record is maintained in the patient's medical record and the practitioner is not the custodian of the medical record, the practitioner shall make the controlled substance record available as required in 19 CSR 30-1.041 and 19 CSR 30-1.044.

(3) Individual practitioners shall maintain the records listed in subsections (1)(A)-(E) of this rule separately from patient medical records.

(4) A registrant who transfers a controlled substance to or receives a controlled substance from another registrant shall maintain a written record of the transfer which contains the following information: the date of transfer, drug name, strength, dosage form, quantity, name, address and registration number of the transferring registrant and the name, address and registration number of the receiving registrant.

(5) Drug Enforcement Administration official order forms shall be used for transfers of Schedule II controlled substances.

(6) A prescription may not be issued for an individual practitioner to obtain controlled substances for dispensing or administering to patients.

(7) Prescriptions which are transmitted by facsimile to a pharmacy for dispensing shall include the telephone number of the facsimile machine or computer from which it is sent and the date and time of transmission. Immediately after a Schedule III, IV or V prescription or a Schedule II prescription for a long-term care facility patient or hospice patient or for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion is transmitted to a pharmacy by facsimile equipment, the practitioner or the practitioner's agent shall sign and date the face of the prescription. The prescriptions shall be maintained in chronological order separately from patient medical records in a manner so each prescription is readily retrievable for inspection at the transmitting practitioner's office. In the event the facsimile is transmitted from a long-term care facility or hospital, the prescription shall be maintained at the long-term care facility or hospital in chronological order separately from the patient medical records in a manner so each prescription is readily retrievable, or maintained in the patient medical records.

(8) Any pharmacy receiving a controlled substance prescription transmitted by facsimile equipment shall maintain the facsimile copy of the prescription along with the date and time of transmission and the telephone number of the facsimile machine from which it originated, as a part of its original prescription records.

(9) Any practitioner or practitioner's agent who transmits a controlled substance prescription by electronic computer transmission shall maintain a printout of each day's transmissions. The practitioner or practitioner's agent shall verify that the information in the printout is correct and shall sign the printout.

(10) Each pharmacist who dispenses controlled substances under a prescription transmitted by electronic computer transmission, shall verify with the practitioner within 30 days of the filling such prescription that the prescription was authorized by the practitioner. If verification is made by telephone, the pharmacist shall document the verification on the reverse of the prescription or in the computer. If verification is made by sending the practitioner a copy of a computer printout, the practitioner shall verify, sign and return the printout to the pharmacy. The pharmacy shall maintain the verified printout in a separate file.

*AUTHORITY: sections 195.050 and 195.195, RSMo 1994.\* Original rule filed April 14, 2000, effective Nov. 30, 2000.*

*\*Original authority: 195.050, RSMo 1939, amended 1971, 1989; 195.195, RSMo 1957, amended 1971, 1989, 1993.*

## **19 CSR 30-1.050 Records for Chemical Analysts**

*PURPOSE: This rule sets requirements for record keeping for chemical analyst registrants.*

(1) Each person registered to conduct chemical analysis with controlled substances shall maintain records with the following information (to the extent known and reasonably ascertainable by him/her) for each controlled substance:

(A) The name of the substance;

(B) The form(s) in which the substance is received, imported or manufactured by the registrant (for example, powder, granulation, tablet, capsule or solution) and the concentration of the substance in that form (for example, Chemically Pure (CP), United States Pharmacopeia (USP), National Formulary (NF), ten milligram (10 mg) tablet or ten milligram (10 mg) concentration per milliliter);

(C) The total number of the forms received, imported or manufactured (for example 100 tablets, 30 one milliliter (1 ml) vials or ten grams (10 g) powder), including the date and quantity of each receipt, importation or manufacture and the name, address and registration number, if any, of the person from whom the substance was received; and

(D) The quantity distributed, exported or destroyed in

any manner by the registrant (except quantities used in chemical analysis or other laboratory work), including the date and manner of distribution, exportation or destruction and the name, address and registration number, if any, of each person to whom the substance was distributed or exported.

(2) Order forms, import and export permits, import invoices and export declarations relating to controlled substances shall be maintained separately from all other records of the registrant.

(3) Records of controlled substances used in chemical analysis or other laboratory work are not required.

(4) Records relating to known or suspected controlled substances received as samples for analysis are not required under section (1) of this rule.

*AUTHORITY: sections 195.050 and 195.195, RSMo 1994.\* Original rule filed April 14, 2000, effective Nov. 30, 2000.*

*\*Original authority: 195.050, RSMo 1939, amended 1971, 1989; 195.195, RSMo 1957, amended 1971, 1989, 1993.*

#### **19 CSR 30-1.052 Records for Long-Term Care Facilities (LTCF)**

*PURPOSE: This rule sets requirements for record keeping by long-term care facility registrants.*

(1) Long-term care facilities (LTCFs) and their suppliers shall maintain written records of transfers of controlled substances from the supplier to the LTCF emergency kit.

(2) The records shall include the date of transfer; the name of each controlled substance, the strength, dosage form and quantity; the name, address and controlled substance registration number of the supplier and the name, address and controlled substance registration number of the LTCF. Federal Drug Enforcement Administration (DEA) official order forms shall not be used to record transfers of controlled substances to LTCF emergency kits.

(3) No physician's order or prescription shall be used for initial stocking or replacement of controlled substances in the emergency kit. Controlled substances contained in the kit shall be obtained from a pharmacy, hospital or practitioner who holds a controlled substances registration.

(4) The administration and medical staff of the LTCF, in conjunction with the primary supplier, shall designate in written protocols and procedures who may have access to the emergency kit, who may administer controlled substances from the emergency kit and under what circumstances and a list of the controlled substances it in-

tends to maintain in the emergency kit. These protocols and procedures shall be subject to review and approval by the Department of Health. Only those individuals designated in the LTCF's written policies and procedures shall have access to or administer controlled substances from the emergency kit.

(5) Each administration of controlled substances from the emergency kit shall be based upon a practitioner's order and shall be recorded in an administration record separate from the patient's medical record. This administration record shall include: the date, patient's name, drug name, drug strength, dosage, ordering practitioner's name and name of the person administering the controlled substance.

*AUTHORITY: sections 195.050 and 195.195, RSMo 1994.\* Original rule filed April 14, 2000, effective Nov. 30, 2000.*

*\*Original authority: 195.050, RSMo 1939, amended 1971, 1989; 195.195, RSMo 1957, amended 1971, 1989, 1993.*

#### **19 CSR 30-1.060 Determining Lawful Prescribing, Dispensing and Administering of Controlled Substances**

*PURPOSE: This rule defines the statutory and regulatory basis for determining what is lawful prescribing, dispensing and administering of controlled substances.*

When determining if controlled substances are being lawfully prescribed, dispensed and administered by practitioners, the Department of Health shall enforce Chapter 195, RSMo, the Department of Health rules in 19 CSR 30 pertaining to controlled substances, and the federal Controlled Substances Act 21 U.S.C. 801-966, and its regulations, 21 CFR 1300-1399. In determining lawful prescribing, dispensing and administering of controlled substances, the Department of Health also shall consider the provisions of Chapters 330, 332, 334, 335, 336, 338 and 340, RSMo, the rules in 4 CSR 110, 4 CSR 150, 4 CSR 200, 4 CSR 210, 4 CSR 220, 4 CSR 230 and 4 CSR 270, and protocols relating to the respective practitioners established and on file at the respective licensing boards.

*AUTHORITY: sections 195.030, RSMo Supp. 1999 and 195.195, RSMo 1994.\* Original rule filed April 14, 2000, effective Nov 30, 2000.*

*\*Original authority: 195.030, RSMo 1939, amended 1971, 1989, 1993, 1995, 1999; 195.195, RSMo 1957, amended 1971, 1989, 1993.*

## 19 CSR 30-1.062 Transmission of Prescriptions

*PURPOSE: This rule sets requirements governing the transmission of prescription information.*

(1) Prescriptions in Schedule II. A pharmacist may dispense a controlled substance in Schedule II only under a written prescription signed by the practitioner, except as provided in section 195.060.3, RSMo. A prescription for a Schedule II controlled substance may be transmitted from the prescribing practitioner to a pharmacy by facsimile equipment or electronic computer transmission, provided the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except that-

(A) A prescription written for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the pharmacy by facsimile or by electronic computer transmission. The facsimile or the computer transmission which has been reduced to writing shall serve as and shall be maintained in the same manner as an original written prescription.

(B) A prescription written for a Schedule II substance for a resident of a long-term care facility may be transmitted by the practitioner or the practitioner's agent to the pharmacy by facsimile or by electronic computer transmission. The facsimile or the computer transmission which has been reduced to writing shall serve as and shall be maintained in the same manner as an original written prescription.

(C) A prescription written for a Schedule II substance for a patient of a hospice may be transmitted by the practitioner or the practitioner's agent to the pharmacy by facsimile or by electronic computer transmission. The practitioner or the practitioner's agent shall note on the prescription that the patient is a hospice patient. The facsimile or the computer transmission which has been reduced to writing shall serve as and shall be maintained in the same manner as an original written prescription.

(2) Prescriptions in Schedule III, IV or V. A pharmacist may dispense directly a controlled substance in Schedule III, IV or V only under a written prescription signed by a practitioner or a facsimile of a written, signed prescription transmitted by the practitioner or his/her authorized agent or under an oral prescription made by an individual practitioner whether communicated by the practitioner or his/her authorized agent or a prescription transmitted by electronic computer transmission by the authorizing practitioner or the practitioner's agent to the pharmacy. All oral prescriptions and prescriptions transmitted by electronic computer transmission shall be promptly reduced to writing by the pharmacist containing all information required in section 195.060, RSMo, except for the signature of the practitioner.

(3) Written Prescriptions. All written controlled substance

prescriptions shall be signed by the prescribing practitioner on the date prescribed. No controlled substance prescription shall be signed prior to the actual date it is issued.

*AUTHORITY: section 195.195, RSMo 1994.\* Original rule filed April 14, 2000, effective Nov. 30, 2000.*

*\*Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

## 19 CSR 30-1.064 Partial Filling of Schedule II Prescriptions

*PURPOSE: This rule sets requirements for the partial filling of Schedule II prescriptions.*

(1) The partial filling of a prescription for a controlled substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and s/he makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

(2) A prescription for a Schedule II controlled substance written for a patient in a long-term care facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist must record on the prescription whether the patient is "terminally ill" or an "LTCF patient." A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been filled in violation of Chapter 195, RSMo. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication.

**AUTHORITY:** section 195.195, RSMo 1994.\* *Original rule filed April 14, 2000, effective Nov. 30, 2000.*

*\*Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

### **19 CSR 30-1.066 Dispensing by Individual Practitioners**

**PURPOSE:** *This rule sets requirements for individual practitioners who dispense controlled substances.*

(1) An individual practitioner who dispenses controlled substances shall—

(A) Provide direct supervision to employees or agents who assist in the administering or dispensing of controlled substances. Controlled substances shall not be dispensed from an individual practitioner's inventory unless a practitioner is physically in the registered location except pursuant to the provisions of section (2) of this rule;

(B) Package all controlled substances dispensed from an individual practitioner's inventory in compliance with the Poison Prevention Packaging Act of 1970, 15 U.S.C. 1471–1476;

(C) Permanently affix a label to the exterior of the drug container which includes: the date, the name and address of the dispensing practitioner, the name of the patient, directions for use, and the exact name and strength of the drug dispensed for all controlled substances dispensed;

(D) Dispense only to individuals with whom the practitioner has established and documented a practitioner/patient relationship. An individual practitioner shall not dispense under the order of another practitioner not practicing at that location.

(2) Mid-level practitioners shall not independently purchase, stock, administer, and dispense controlled substances. Controlled substances may be administered or dispensed from an individual practitioner's inventory by a mid-level practitioner with whom he or she has entered into an agreement pursuant to Chapter 334, RSMo, when the practitioner is not present at the registered location.

**AUTHORITY:** section 195.195, RSMo 2000.\* *Original rule filed April 14, 2000, effective Nov. 30, 2000. Amended: Filed April 29, 2011, effective Nov. 30, 2011.*

*\*Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

### **19 CSR 30-1.068 Administering In Emergency Rooms**

**PURPOSE:** *This rule sets requirements for administering controlled substances in hospital emergency rooms.*

(1) Controlled substances may be administered to a hospital emergency room patient under a verbal order of a registered practitioner who is not physically present if—

(A) The order is for a legitimate medical purpose and the practitioner who orders the administration of a controlled substance is acting in the usual course of his/her medical practice, after sufficient examination and establishment of a practitioner/patient relationship;

(B) The practitioner who orders the administration of a controlled substance is a medical staff member of the hospital;

(C) The administration of a controlled substance is documented in a formal medical record for the patient;

(D) The patient is assessed in the hospital by a practitioner, when available, or a registered nurse. If the patient is not assessed by a practitioner in the hospital, a registered nurse shall assess the patient and confirm and document in the patient's medical record the existence of a preestablished practitioner/patient relationship with the practitioner who ordered administration of a controlled substance;

(E) The order is written in the patient's medical record and is authenticated by the ordering practitioner within a time frame and manner as defined by the medical staff in cooperation with nursing and administration. This policy shall be included in the hospital's written policies and procedures.

**AUTHORITY:** section 195.195, RSMo 1994.\* *Original rule filed April 14, 2000, effective Nov. 30, 2000.*

*\*Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

### **19 CSR 30-1.070 Emergency Dispensing of Schedule II Substances**

**PURPOSE:** *This rule provides for the prescribing and dispensing of Schedule II drugs in an emergency situation.*

(1) In the case of a bona fide emergency situation, as defined by the Department of Health, a pharmacist may dispense a Schedule II controlled substance upon receiving oral authorization of a prescribing practitioner; provided, that—

(A) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period. Prescribing or dispensing beyond the emergency period must be pursuant to a written prescription;

(B) The prescription immediately shall be reduced to writing by the pharmacist and shall contain all information, except for the prescribing practitioner's signature;

(C) If the prescribing practitioner is not known to the pharmacist, s/he must make reasonable effort to determine that the oral authorization came from a practitioner, by verifying his/her phone number against that listed in the directory and other good faith efforts to insure his/her identity;

(D) Within seven days after authorizing an emergency oral prescription, the prescribing practitioner must cause a written prescription for the emergency quantity pre-

scribed to be delivered to the dispensing pharmacist. The prescription shall have written on its face authorization for emergency dispensing. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the seven-day period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had

earlier been reduced to writing. The pharmacist shall notify the Department of Health if the prescribing practitioner fails to deliver a written prescription to him/her; failure of the pharmacist to do so shall void the authority conferred by this section to dispense without a written prescription of a prescribing practitioner.

(2) Definition of Emergency Situation. For the purpose of authorizing an oral prescription of a controlled substance listed in Schedule II of the controlled substances law (sections 195.010-195.320, RSMo), the term emergency situation means those situations in which the prescribing practitioner determines that-

(A) Immediate administration of a controlled substance is necessary for proper treatment of the intended ultimate user;

(B) No appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under Schedule II;

(C) It is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance prior to the dispensing.

*AUTHORITY: section 195.195, RSMo 1994.\* Original rule filed April 14, 2000, effective Nov. 30, 2000.*

*\*Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

### **19 CSR 30-1.072 Dispensing of Schedule V Substances**

*PURPOSE: This rule provides for the prescribing, administering and dispensing of Schedule V drugs.*

(1) A pharmacist may dispense directly a controlled substance listed in Schedule V pursuant to a prescription. A prescription for a controlled substance listed in Schedule V may be refilled only as expressly authorized by the prescribing individual practitioner. If this authorization is not given, the prescription may not be refilled. A pharmacist dispensing those substances pursuant to a prescription shall label the substance and file the prescription.

(2) An individual practitioner may administer or dispense directly a controlled substance listed in Schedule V in the course of his/her professional practice without a prescription.

(3) An institutional practitioner may administer or dis-

pense directly (but not prescribe) a controlled substance listed in Schedule V only pursuant to a written prescription signed by the prescribing individual practitioner or pursuant to an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist (containing all information required except for the signature of the prescribing individual practitioner) or pursuant to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user.

*AUTHORITY: section 195.195, RSMo 1994.\* Original rule filed April 14, 2000, effective Nov. 30, 2000.*

*\*Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

### **19 CSR 30-1.074 Dispensing Without a Prescription**

*PURPOSE: This rule provides for dispensing Schedule V controlled substances without a prescription in certain situations.*

(1) Definitions. For the purposes of this rule, the following terms shall apply:

(A) "Dispenser" means a pharmacist, intern pharmacist, or registered pharmacy technician who sells, dispenses, or otherwise provides methamphetamine precursor products to purchasers.

(B) "Methamphetamine precursor products" means both Schedule V pseudoephedrine products and any other drug product containing any detectable amount of ephedrine, pseudoephedrine, or phenylpropanolamine, including the salts or optical isomers or salts of optical isomers or ephedrine, its salts or optical isomers, or salts of optical isomers of ephedrine, pseudoephedrine, or phenylpropanolamine.

(C) "Valid photo identification" means a photo identification that is issued by a state or the federal government or a document that, with respect to identification, is considered acceptable and showing the date of birth of the person, including forms of identification acceptable under federal regulations 8 CFR 274a.2(b)(1)(v)(A) and (B).

(2) Dispensing Without a Prescription. A controlled substance listed in Schedule V which is not a prescription drug under the federal Food, Drug and Cosmetic Act, and is not a methamphetamine precursor product, may be dispensed by a pharmacist without a prescription to a purchaser at retail; provided, that—

(A) Dispensing is made only by a pharmacist and not by a non-pharmacist employee even if under the supervision of a pharmacist (although after the pharmacist has fulfilled his/her professional and legal responsibilities, the actual cash transaction, credit transaction, or delivery may be completed by a non-pharmacist); and

(B) Dispensing, sale, distribution, or otherwise providing is limited to not more than two hundred forty cubic centimeters (240 cc) or eight ounces (8 oz.) of any con-

trolled substance containing opium, nor more than one hundred twenty cubic centimeters (120 cc) or four ounces (4 oz.) of any other controlled substance, nor more than forty-eight (48) dosage units of any controlled substance containing opium, nor more than twenty-four (24) dosage units of any other controlled substance may be dispensed at retail to the same purchaser in any given forty-eight (48)-hour period.

(3) Methamphetamine precursor products may be sold, dispensed, distributed, or otherwise provided only as follows:

(A) Products that are designated Schedule V controlled substances which contain any detectable amount of pseudoephedrine, ephedrine, phenylpropanolamine, their salts or optical isomers, or salts of their optical isomers may be sold, distributed, or otherwise provided only by a pharmacist or pharmacy ancillary personnel as authorized by the Missouri State Board of Pharmacy;

(B) Dispensers of methamphetamine precursor products shall exercise reasonable care in assuring that the purchaser has not exceeded the three and six-tenths (3.6)-gram limit per day or the nine (9)-gram limit per thirty (30)-day period;

(C) Dispensers shall utilize the real-time electronic pseudoephedrine tracking system established and maintained by the Missouri Department of Health and Senior Services (DHSS);

(D) Methamphetamine precursor products regulated by Missouri law as controlled substances shall only be sold to customers eighteen (18) years of age or older who present a valid photo identification;

(E) Any dispenser who sells, dispenses, or otherwise provides any methamphetamine precursor product shall submit the following information to the DHSS electronic database at the time of purchase:

1. Date and time of transaction;
2. Pharmacy identification information, including:
  - A. National Council for Prescription Drug Programs identification number; or
  - B. National Association of Boards of Pharmacy identification number; or
  - C. Vendor assigned site and/or pharmacy identifier;
3. Purchaser information, including the following fields:
  - A. Purchaser's given or first name;
  - B. Purchaser's middle name (if any);
  - C. Purchaser's surname or last name;
  - D. The purchaser's full name shall be entered into the database without the use of initials or nicknames;
  - E. Purchaser's date of birth; and
  - F. Purchaser's address, including number, street, city, state, and zip code;
4. Identification of the form of valid photo identification presented by the purchaser; including issuing agency of the photo identification and identification number appearing on the photo identification;
5. Purchaser's signature;
6. Dispenser identification, including:
  - A. The name of the individual performing the transaction; or

B. The initials of the individual performing the transaction;

7. Transaction number, assigned by the database provider/vendor;

8. Purchase transaction information, including the following:

- A. Product Universal Product Code (UPC);
- B. Product National Drug Code (NDC) (optional);
- C. Unique product description; and
- D. Purchase quantity, in grams as—

(I) Product grams per box and number of boxes in transaction;

(II) Product grams per dosage form such as tablet, capsule, or milliliter, and number of dosages per transaction; or

(III) Other mechanism identified by the database provider/vendor; and

9. Form of pseudoephedrine in a manner defined by the database provider/vendor, including but not limited to:

- A. Tablet;
- B. Capsule;
- C. Liquid-filled gelcap; or
- D. Liquid;

(F) Purchaser information provided and entered into the DHSS electronic database shall be the same as that on the presented identification. Full names shall be used and not merely initials or a nickname;

(G) If the DHSS electronic database is not available at the time of the sale of the methamphetamine precursor product, the information to be provided in subsection (3) (E) above shall be recorded manually and entered into the DHSS electronic database as soon as practicable after the system is back online, as specified in subsection (3)(I). Signatures shall be captured on paper and then may be scanned to the database;

(H) Every dispenser who sells, dispenses or otherwise provides any methamphetamine precursor product shall maintain a bound logbook in addition to the electronic database system. The logbook shall be used for documenting a clear audit trail of any alterations, changes, or deletions to the original transaction record, and sales that occurred during system failures, including date and time of entry into the database, justification, and resultant contacts with law *enforcement because the override button was used*;

(I) In the event that the DHSS electronic database is unavailable for five (5) minutes or more due to a failure on the DHSS network or because of a failure attributable to systems other than the DHSS, the dispenser may continue with the transaction until the system is available. All information required to be captured with each transaction shall be retained and documented. The information may be entered into the database where it may be held pending until the system comes back on line, or all of the required information for transactions occurring during the time the DHSS electronic database is unavailable must be recorded manually and entered into the DHSS electronic database by the registrant as soon as is practicable, but within no more than forty-eight (48)



hours following the resumption of operability. Documentation shall also identify the reason for the late entry into the DHSS electronic database;

(J) At least once each month, the pharmacist-in-charge shall review the logbook of changes and the changes captured by the database to see what changes and alterations pharmacy employees have entered regarding sales of methamphetamine precursors. The date and time that the pharmacist-in-charge conducts this monthly review shall be documented in the bound logbook maintained by the pharmacy in addition to the electronic system;

(K) Documentation in the bound logbook shall be maintained in a readily retrievable manner for two (2) years from the date of the transaction and available for inspection and copying by authorized DHSS employees and law enforcement;

(L) Denials of Sales and Dispensings.

1. Except as provided in subsection (D) of this section, if an individual attempts to purchase a methamphetamine precursor product in violation of the three and six-tenths (3.6) gram per day or nine (9) gram per month quantity restrictions or age restriction established by sections 195.017 and 195.417, RSMo, the dispenser shall refuse to make the sale. The purchaser must be at least eighteen (18) years of age.

2. Sales of methamphetamine precursor products shall be denied to purchasers who are not able to produce a valid government issued identification card with the required information displayed on it.

3. In the event that the dispenser perceives that refusal of the purchase may place him or her in imminent physical harm, then the dispenser may use the database safety override function to proceed with the transaction, provided that—

A. When jeopardy is no longer perceived, the dispenser shall immediately contact local law enforcement to report the purchase; and

B. The dispenser shall document in their manual log, the circumstance, the individual contacted at the local law enforcement agency, and the date and time of that contact;

(M) Pharmacy Employees. Employees in a pharmacy shall be assigned individual personal passwords to identify their own transactions in the database.

1. Pharmacy employees shall only use their own passwords for their own transactions and shall not dispense or make a sale under the password of another person.

2. The database computer shall not be left on and unattended so that another person can use the previous user's password. Users shall close out their personal access when their activities are completed.

3. The pharmacist-in-charge shall be responsible for insuring pharmacy employees have adequate password privileges. The pharmacist-in-charge shall insure that new employees have their own personal passwords and also insure that ex-employees have their passwords removed from the system;

(N) Access to Database by Law Enforcement and Reg-

ulatory Agencies.

1. Access to the database and controlled substance records shall be made available to those agencies with authority under Chapter 195 and Chapter 338, RSMo.

2. Law enforcement agencies and regulatory agencies shall only have the ability to read and review and shall not be able to enter data or change records.

3. It shall be the responsibility of each agency's administrator, chief, sheriff, or other chief executive officer to insure—

A. Only authorized employees have access to the database;

B. Employees only use their own passwords and passwords are not shared;

C. Each employee adheres to all state and federal laws regarding confidentiality; and

D. As employees change, that new passwords are assigned to new employees and passwords of ex-employees or transferred employees are removed. The chief, sheriff, or chief executive officer of the law enforcement or regulatory agency shall notify the DHSS in writing when an employee's access is to be added or removed; and

(O) Method for Enforcement Agencies to Gain or Alter Access to the Database.

1. Requests submitted to the DHSS to add or remove an employee from access to the database shall—

A. Be submitted in writing on the agency's letterhead;

B. State whether this is a request for an employee to be granted access to the database or a request to remove an employee's access;

C. Provide the employee's full name and title;

D. Provide the employee's Missouri POST certification number if the employee is a sworn law enforcement officer; and

E. Be signed by the chief, sheriff, or chief executive officer of the requesting agency.

2. Multiple requests for multiple employees and actions may be submitted on one (1) letter.

3. The DHSS shall notify the provider of the database in writing of persons who are given access or have access removed.

4. The DHSS may restrict access to the database to a limited number of people in each agency, depending on the size of the agency, their locations, and number of sworn officers engaged in the actual enforcement of controlled substance laws.

*AUTHORITY: sections 195.017 and 195.417, RSMo Supp. 2010 and sections 195.030, 195.050, and 195.195, RSMo 2000.\* Original rule filed April 14, 2000, effective Nov. 30, 2000. Emergency amendment filed Aug. 18, 2005, effective Aug. 28, 2005, expired Feb. 23, 2006. Amended: Filed Sept. 1, 2005, effective Feb. 28, 2006. Emergency amendment filed July 9, 2010, effective Sept. 28, 2010, expired March 26, 2011. Amended: Filed June 29, 2010, effective Jan. 30, 2011.*

\*

*Original authority: 195.017, RSMo 1971, amended*

1987, 1989, 1994, 1996, 1997, 1998, 2001, 2005, 2006, 2008; 195.030, RSMo 1939, amended 1971, 1989, 1993, 1995, 1997, 1999; 195.050, RSMo 1939, amended 1971, 1989; 195.195, RSMo 1957, amended 1971, 1989, 1993; and 195.417, RSMo 2001, amended 2003, 2005, 2008.

### **19 CSR 30-1.076 Emergency Distribution by a Pharmacy**

*PURPOSE: This rule provides for dispensing of controlled substances by a pharmacy in emergency situations.*

(1) An emergency means a situation where a quantity of a controlled substance must be dispensed by a pharmacy to a patient who does not have an alternative source for that substance reasonably available to him/her and the pharmacy cannot obtain that substance through its normal distribution channels within the time required to meet the immediate needs of the patient for that substance. In the event of an emergency, a pharmacy may distribute (without being registered as a distributor) a controlled substance in Schedule III, IV or V to a second pharmacy in order for that pharmacy to dispense the substance; provided, that-

(A) The amount distributed does not exceed the amount required by the second pharmacy for his/her immediate dispensing;

(B) The distribution is recorded as being dispensed by the first pharmacy and the second pharmacy records the substance as being received. Each pharmacy will retain a signed receipt of the distribution;

(C) The second pharmacy is registered to dispense the controlled substance to be distributed to him/her;

(D) If the substance is a Schedule II controlled substance, the official order form designated by the federal Drug Enforcement Administration must be used to document the transfer.

*AUTHORITY: section 195.195, RSMo 1994.\* Original rule filed April 14, 2000, effective Nov. 30, 2000.*

*\*Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

### **19 CSR 30-1.078 Disposing of Unwanted Controlled Substances**

*PURPOSE: This rule establishes procedures for disposing of unwanted controlled substances.*

(1) A registrant in possession of any controlled substance(s) and desiring or required to dispose of such substance(s) shall:

(A) Return the controlled substances to the original supplier;

(B) Transfer the controlled substances to a distributor authorized to accept controlled substances for the purpose of disposal;

(C) Submit a DEA Form 41 to the federal Drug Enforcement Administration requesting authorization to dispose of the controlled substances in compliance with federal regulations;

(D) Contact the Bureau of Narcotics and Dangerous Drugs (BNDD), Department of Health for information pertaining to subsections (1)(A), (B) or (C).

(2) The return, transfer or disposal of any controlled substance shall be documented in accordance with 19 CSR 30-1.044.

(3) In the event the registrant is a hospital, the following procedures are to be used for the destruction of controlled substances:

(A) When disposal of controlled substances is in patient care areas-

1. Controlled substances which are contaminated by patient body fluids are to be destroyed by a physician, nurse or a pharmacist in the presence of another hospital employee;

2. An excess volume of a controlled substance which must be discarded from a dosage unit just prior to use shall be destroyed by a nurse, pharmacist or physician in the presence of another hospital employee;

3. The remaining contents of opened glass ampules of controlled substances shall be destroyed by a nurse, pharmacist or physician in the presence of another hospital employee;

4. Single units of single dose packages of controlled substances which are contaminated other than by patient body fluids and are not an infectious hazard, or have been removed from their original or security packaging, or are partially used, or are otherwise rendered unsuitable for patient use shall be destroyed by a nurse, pharmacist or physician in the presence of another hospital employee or returned to the pharmacy for destruction;

5. The following shall be entered in the controlled substance administration record or a separate controlled substance destruction record when the controlled substance is destroyed in the patient care area: the date and hour of destruction, the drug name and strength, the amount destroyed, the reason for destruction and the patient's name and room number. The nurse, pharmacist or physician and the witnessing hospital employee shall sign the entry. The drug shall be destroyed so that it is beyond reclamation. The controlled substance administration or destruction records are to be retained for two years and available for inspection by Department of Health investigators;

6. All other controlled substances which are not patient contaminated but which are to be disposed of shall be returned to the pharmacy for disposal;

(B) When disposal of controlled substances is in the pharmacy-

1. Single units of controlled substances which are contaminated other than by patient body fluids and are not an infectious hazard, or have been removed from their original or security packaging, or are partially used, or are otherwise rendered unsuitable for patient use shall

be destroyed by a pharmacist in the presence of another hospital employee or held for later destruction;

2. All other controlled substances which are not patient contaminated but are to be disposed of shall be placed in a suitable container for storage and disposed of as described in section (1) of this rule.

(4) If the registrant administers controlled substances and is not a hospital, the following procedures are to be used for the destruction of controlled substances:

(A) Controlled substances which are contaminated by patient body fluids are to be destroyed, in the presence of another employee, by the registrant or designee authorized to administer;

(B) An excess volume of a controlled substance which must be discarded from a dosage unit just prior to use is to be destroyed, in the presence of another employee, by the registrant or designee authorized to administer;

(C) The remaining contents of opened glass ampules of controlled substances which are not patient contaminated are to be destroyed, in the presence of another employee, by the registrant or designee authorized to administer;

(D) When the controlled substance is destroyed by the registrant or designee authorized to administer, the following shall be entered in the controlled substances administration records or a separate controlled substances destruction record: the date and amount destroyed, the reason for destruction and the registrant's name and address. The registrant or designee doing the destruction and the witnessing employee shall sign the entry. The drug shall be destroyed so that it is beyond reclamation. The controlled substances administration or destruction records are to be retained for two years and available for inspection by Department of Health investigators;

(E) All other controlled substances which are not patient-contaminated but are to be disposed of shall be placed in a suitable container for storage and disposed of as described in section (1) of this rule.

*AUTHORITY: sections 195.050 and 195.195, RSMo 1994.\* Original rule filed April 14, 2000, effective Nov. 30, 2000.*

*\*Original authority: 195.050, RSMo 1939, amended 1971, 1989; 195.195, RSMo 1957, amended 1971, 1989, 1993.*



# HOSPITAL REGULATIONS



## **19 CSR 30-20.100 Pharmacy Services and Medication Management in Hospitals**

*PURPOSE: This rule establishes the requirements for pharmacy services and medication management in a hospital.*

(1) Pharmacy services shall be identified and integrated within the total hospital organizational plan. Pharmacy services shall be directed by a pharmacist who is currently licensed in Missouri and qualified by education and experience. The director of pharmacy services shall be responsible for the provision of all services required in subsection (4)(G) of this rule and shall be a participant in all decisions made by pharmacy services or committees regarding the use of medications. With the assistance of medical, nursing and administrative staff, the director of pharmacy services shall develop standards for the selection, distribution and safe and effective use of medications throughout the hospital.

(2) Additional professional and supportive personnel shall be available for services provided. Pharmacists shall be currently licensed in Missouri and all personnel shall possess the education and training necessary for their responsibilities.

(3) Support pharmacy personnel shall work under the supervision of a pharmacist and shall not be assigned duties that by law must be performed by a pharmacist. Interpreting medication orders, selecting, compounding, packaging, labeling and the dispensing of medications by pharmacy staff shall be performed by or under the supervision of a pharmacist. Interpretation of medication orders by support personnel shall be limited to order processing and shall not be of a clinical nature.

(4) Hours shall be established for the provision of pharmacy services. A pharmacist shall be available to provide required pharmacy services during hours appropriate for necessary contact with medical and nursing staff. A pharmacist shall be on call at all other times.

(5) Space, equipment and supplies shall be available according to the scope of pharmacy services provided. Office or other work space shall be available for administrative, clerical, clinical and other professional services provided. All areas shall meet standards to maintain the safety of personnel and the security and stability of medications stored, handled and dispensed.

(6) The pharmacy and its medication storage areas shall have proper conditions of sanitation, temperature, light, moisture, ventilation and segregation. Refrigerated medication shall be stored separate from food and other substances. The pharmacy and its medication storage area shall be locked and accessible only to authorized pharmacy and supervisory nursing personnel. The director of pharmacy services, in conjunction with nursing and administration, shall be responsible for the authori-

zation of access to the pharmacy by supervisory nursing personnel to obtain doses for administering when pharmacy services are unavailable.

(7) Medication storage areas outside of the pharmacy shall have proper conditions of sanitation, temperature, light, moisture, ventilation and segregation. Refrigerated medications shall be stored in a sealed compartment separate from food and laboratory materials. Medication storage areas shall be accessible only to authorized personnel and locked when appropriate.

(8) The evaluation, selection, source of supply and acquisition of medications shall occur according to the hospital's policies and procedures. Medications and supplies needed on an emergency basis and necessary medications not included in the hospital formulary shall be acquired according to the hospital's policies and procedures.

(9) Records shall be maintained of medication transactions, including: acquisition, compounding, repackaging, dispensing or other distribution, administration and controlled substance disposal. Persons involved in compounding, repackaging, dispensing, administration and controlled substance disposal shall be identified and the records shall be retrievable. Retention time for records of bulk compounding, repackaging, administration, and all controlled substance transactions shall be a minimum of two (2) years. Retention time for records of dispensing and extemporaneous compounding, including sterile medications, shall be a minimum of six (6) months.

(10) Security and record keeping procedures in all areas shall ensure the accountability of all controlled substances, shall address accountability for other medications subject to theft and abuse and shall be in compliance with 19 CSR 30-1.030(3). Inventories of Schedule II controlled substances shall be routinely reconciled. Inventories of Schedule III-V controlled substances outside of the pharmacy shall be routinely reconciled. Records shall be maintained so that inventories of Schedule III-V controlled substances in the pharmacy shall be reconcilable.

(11) Controlled substance storage areas in the pharmacy shall be separately locked and accessible only to authorized pharmacy staff. Reserve supplies of all controlled substances in the pharmacy shall be locked. Controlled substance storage areas outside the pharmacy shall be separately locked and accessible only to persons authorized to administer them and to authorized pharmacy staff.

(12) Authorization of access to controlled substance storage areas outside of the pharmacy shall be established by the director of pharmacy services in conjunction with nursing and administration. The distribution and accountability of keys, magnetic cards, electronic codes or other mechanical and electronic devices shall occur

according to the hospital's policies and procedures.

(13) All variances involving controlled substances—including inventory, security, record keeping, administration and disposal—shall be reported to the director of pharmacy services for review and investigation. Loss, diversion, abuse or misuse of medications shall be reported to the director of pharmacy services, administration, and local, state and federal authorities as appropriate.

(14) The provision of pharmacy services in the event of a disaster, removal from use of medications subject to product recall and reporting of manufacturer drug problems shall occur according to the hospital's policies and procedures.

(15) Compounding and repackaging of medications in the pharmacy shall be done by pharmacy personnel under the supervision of a pharmacist. Those medications shall be labeled with the medication name, strength, lot number, expiration date and other pertinent information. Record keeping and quality control, including end-product testing when appropriate, shall occur according to the hospital's policies and procedures.

(16) Compounding, repackaging or relabeling of medications by nonpharmacy personnel shall occur according to the hospital's policies and procedures. Medications shall be administered routinely by the person who prepared them, and preparation shall occur just prior to administration except in circumstances approved by the director of pharmacy, nursing and administration. Compounded sterile medications for parenteral administration prepared by nonpharmacy personnel shall not be administered beyond twenty-four (24) hours of preparation. Labeling shall include the patient's name, where appropriate, medication name, strength, beyond use date, identity of the person preparing and other pertinent information.

(17) Compounded sterile medications shall be routinely prepared in a suitably segregated area in a Class 100 environment by pharmacy personnel. Preparation by nonpharmacy personnel shall occur only in specific areas or in situations when immediate preparation is necessary and pharmacy personnel are unavailable and shall occur according to policies and procedures. All compounded cytotoxic/hazardous medications shall be prepared in a suitably segregated area in a Class II biological safety cabinet or vertical airflow hood. The preparation, handling, administration and disposal of sterile or cytotoxic/hazardous medications shall occur according to policies and procedures including: orientation and training of personnel, aseptic technique, equipment, operating requirements, environmental considerations, attire, preparation of parenteral medications, preparation of cytotoxic/hazardous medications, access to emergency spill supplies, special procedures/products, sterilization, extemporaneous preparations and quality control.

(18) Radiopharmaceuticals shall be acquired, stored, handled, prepared, packaged, labeled, administered and disposed of according to the hospital's policies and procedures and only by or under the supervision of personnel who are certified by the Nuclear Regulatory Commission.

(19) A medication profile for each patient shall be maintained and reviewed by the pharmacist and shall be reviewed by the pharmacist upon receiving a new medication order prior to dispensing the medication. The pharmacist shall review the prescriber's order or a direct copy prior to the administration of the initial dose, except in an emergency or when the pharmacist is unavailable, in which case the order shall be reviewed within seventy-two (72) hours.

(20) Medications shall be dispensed only upon the order of an authorized prescriber with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved policy/protocol after an assessment for contraindications, and only dispensed by or under the supervision of the pharmacist.

(21) All medications dispensed for administration to a specific patient shall be labeled with the patient name, drug name, strength, expiration date and, when applicable, the lot number and other pertinent information.

(22) The medication distribution system shall provide safety and accountability for all medications, include unit of use and ready to administer packaging, and meet current standards of practice.

(23) To prevent unnecessary entry to the pharmacy, a locked supply of routinely used medications shall be available for access by authorized personnel when the pharmacist is unavailable. Removal of medications from the pharmacy by authorized supervisory nursing personnel, documentation of medications removed, restricted and unrestricted medication removal, later review of medication orders by the pharmacist, and documented audits of medications removal shall occur according to the hospital's policies and procedures. The nurse shall remove only amounts necessary for administering until the pharmacist is available.

(24) Floorstock medications shall be limited to emergency and nonemergency medications which are authorized by the director of pharmacy services in conjunction with nursing and administration. The criteria, utilization and monitoring of emergency and non-emergency floorstock medications shall occur according to the hospital's policies and procedures. Supplies of emergency medications shall be available in designated areas.

(25) All medication storage areas in the hospital shall be inspected at least monthly by a pharmacist or designee according to the hospital's policies and procedures.



(26) The pharmacist shall be responsible for the acquisition, inventory control, dispensing, distribution and related documentation requirements of investigational medications according to the hospital's policies and procedures. A copy of the investigational protocol shall be available in the pharmacy to all health care providers who prescribe or administer investigational medications. The identity of all recipients of investigational medications shall be readily retrievable.

(27) Sample medications shall be received and distributed by the pharmacy according to the hospital's policies and procedures.

(28) Dispensing of medications by the pharmacist to patients who are discharged from the hospital or who are outpatients shall be in compliance with 4 CSR 220.

(29) Persons other than the pharmacist may provide medications to patients leaving the hospital only when prescription services from a pharmacy are not reasonably available. Medications shall be provided according to the hospital's policies and procedures, including: circumstances when medications may be provided, practitioners authorized to order, specific medications and limited quantities, prepackaging and labeling by the pharmacist, final labeling to facilitate correct administration, delivery, counseling and a transaction record. Final labeling, delivery and counseling shall be performed by the prescriber or a registered nurse.

(30) Current medication information resources shall be maintained in the pharmacy and patient care areas. The pharmacist shall provide medication information to the hospital staff as requested.

(31) The director of pharmacy services shall be an active member of the pharmacy and therapeutics committee or its equivalent, which shall advise the medical staff on all medication matters. A formulary shall be established which includes medications based on an objective evaluation of their relative therapeutic merits, safety and cost and shall be reviewed and revised on a continual basis. A medication use evaluation program shall be established which evaluates the use of selected medications to ensure that they are used appropriately, safely and effectively. Follow-up educational information shall be provided in response to evaluation findings.

(32) The pharmacist shall be available to participate with medical and nursing staff regarding decisions about medication use for individual patients, including: not to use medication therapy; medication selection, dosages, routes and methods of administration; medication therapy monitoring; provision of medication-related information; and counseling to individual patients. The pharmacist or designee shall personally offer to provide medication counseling when discharge or outpatient prescriptions are filled. The pharmacist shall provide requested counseling.

(33) Medication orders shall be initiated or modified only by practitioners who have independent statutory authority to prescribe or who are legally given authority to order medications. That authority may be given through an arrangement with a practitioner who has independent statutory authority to prescribe and who is a medical staff member. The authority may include collaborative practice agreements, protocols or standing orders and shall not exceed the practitioner's scope of practice. Practitioners given this authority who are not hospital employees shall be approved through the hospital credentialing process. When hospital-based agreements, protocols or standing orders are used, they shall be approved by the pharmacy and therapeutics or equivalent committee.

(34) All medication orders shall be written in the medical record and signed by the ordering practitioner with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy/protocol after an assessment for contraindications. When medication therapy is based on a protocol or standing order and a specific medication order is not written, a signed copy of the protocol or of an abbreviated protocol containing the medication order parameters or of the standing order shall be placed in the medical record with the exception of physician-approved policies/protocols for the administration of influenza and pneumococcal polysaccharide vaccines after an assessment for contraindications. The assessment for contraindications shall be dated and signed by the registered nurse performing the assessment and placed in the medical record. Telephone or verbal orders shall be accepted only by authorized staff, immediately written and identified as such in the medical record and signed by the ordering practitioner within a time frame defined by the medical staff.

(35) Medication orders shall be written according to policies and procedures and those written by persons who do not have independent statutory authority to prescribe shall be included in the quality improvement program.

(36) Automatic stop orders for all medications shall be established and shall include a procedure to notify the prescriber of an impending stop order. A maximum stop order shall be effective for all medications which do not have a shorter stop order. Automatic stop orders are not required when the pharmacist continuously monitors medications to ensure that they are not inappropriately continued.

(37) Medications shall be administered only by persons who have statutory authority to administer or who have been trained in each pharmacological category of medication they administer, and administration shall be limited to the scope of their practice. Persons who do not have statutory authority to administer shall not administer parenteral medications, controlled substances or medications that require professional assessment at the time of administration. A person who has statutory au-

thority to administer shall be readily available at the time of administration. Training for persons who do not have statutory authority to administer shall be documented and administration by those persons shall be included in the quality improvement program. Medications shall be administered only upon the order of a person authorized to prescribe or order medications. Administration by all persons shall occur according to the hospital's policies and procedures.

(38) Medications brought to the hospital by patients shall be handled according to policies and procedures. They shall not be administered unless so ordered by the prescriber and identified by the pharmacist or the prescriber.

(39) Medications shall be self-administered or administered by a responsible party only upon the order of the prescriber and according to policies and procedures.

(40) Medication incidents, including medication errors shall be reported to the prescriber and the appropriate manager. Medication incidents shall be reported to the appropriate committee. Adverse medication reactions shall be reported to the prescriber and the director of the pharmacy services. The medication administered and medication reaction shall be recorded in the patient's medical record. Adverse medication reactions shall be reviewed by the pharmacy and therapeutics committee and other medical or administrative committees when appropriate.

*AUTHORITY: sections 192.006 and 197.080, RSMo 2000 and 197.154, RSMo Supp. 2007.\* This rule previously filed as 19 CSR 30-20.021(3)(G). Original rule filed June 27, 2007, effective Feb. 29, 2008.*

*\*Original authority: 192.006, RSMo 1993, amended 1995; 197.080, RSMo 1953, amended 1993, 1995; and 197.154, RSMo 2004.*

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\* These statutes/regulations are promulgated by and under the jurisdiction of the Missouri Department of Health and Senior Services. The listing provided is only an excerpt of selected provisions. Please refer to Chapter 195, RSMo, and 19 CSR 30, in their entirety for all applicable statutes/regulations.

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 Transfer of Drugs/ Records 20 CSR 2220-5.025(2)

#### **Therapeutic Substitution**

Prohibited When 338.010.10

#### **Transfer of Prescriptions (New)** 20 CSR 2220-6.030 (4)(5)

#### **Transfer of Prescriptions (Refills)**

Electronic Transfers 20 CSR 2220-2.120(2)(B)10.,  
 20 CSR 2220-2.120(2)(C)  
 Mandatory Transfer 20 CSR 2220-2.120(1)  
 Records Required 20 CSR 2220-2.120(2)  
 Timeframe 20 CSR 2220-2.120(3)

### **V**

#### **Vacuum Tube Drug Delivery Systems**

Allowed use of 20 CSR 2220-2.800(1)  
 Audio/Visual System, Required When  
 20 CSR 2220-2.800(1)(C)  
 Exemptions 20 CSR 2220-2.800(2)  
 Lighting 20 CSR 2220-2.800(1)(C)3.

Monitoring of 20 CSR 2220-2.800(1)(C)  
 Pharmacist on Duty 20 CSR 2220-2.800(1)(B)  
 Security 20 CSR 2220-2.800(1)(A)

#### **Veterinary Pharmacy**

Exemptions 338.220.4 - .5  
 License Required 338.220.1(12)  
 Standards of Operation 20 CSR 2220-2.675

### **W**

**Warehouses** 20 CSR 2220-5.020(1)(A)  
 (Chain Drug, Distributor, Manufacturer, Wholesale Drug)

**Well-Being Program** 338.380, 20 CSR 2220-2.175

#### **Wholesale Drug Distributor**

Definitions 338.330  
 (See also Drug Distributors and OOS  
 Wholesale Drug Distributors)





